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## The Implementation of Diabetic Foot Care into Primary Care

Shelby D. Strong

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**VALPO**

**THE IMPLEMENTATION OF DIABETIC FOOT CARE INTO PRIMARY CARE**

by

**SHELBY D. STRONG**

**EVIDENCE-BASED PRACTICE PROJECT REPORT**

Submitted to the College of Nursing and Health Professions

of Valparaiso University,

Valparaiso, Indiana

in partial fulfillment of the requirements

For the degree of

**DOCTOR OF NURSING PRACTICE**

2020

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Student

Date

Advisor

Date

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## **DEDICATION**

This project is dedicated to my father Mr. Danny C. Gibson Sr., my brother Danny C. Gibson Jr., my brother Brian D. Gibson, my nephew Eric Gibson, my aunt Sherita Gibson, and my uncle Olrich (Ricky) Gibson Jr., all of whom have endured the challenges of diabetes with bravery and determination. I love each one of you!

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## ABSTRACT

Diabetes mellitus (DM) is one of the most common metabolic diseases worldwide. It can lead to complications in many parts of the body and can increase overall risk of dying prematurely (World Health Organization (WHO), 2016). Diabetic peripheral neuropathy (DPN) in the feet is one of the most frequent complications of DM (Wang et al., 2017). Other lower extremity complications which can occur as a result of diabetic foot complication (DFC) includes peripheral artery disease (PAD), infection, ulcer and amputation. One of the obstacles for preventing (DFC) is the lack of examinations of the feet in clinical practice (Feitosa et al., 2016). Guided by the Iowa Model Revised (Iowa Model Collaborative, 2017), The purpose of this 12-week project was to implement best practice recommendations for the provision of diabetic foot care into primary care. A review of literature was performed by the project leader (PL) which generated 11 pieces of relevant evidence that met the inclusion criteria. Participants of this project included 531 adult diabetic patients, ages 18-74, who were seen in the primary care setting. Best practice recommendation for interventions included: (a) provider history and foot physical assessment including provider use of the Semmes-Weinstein Monofilament (SWM) tool to assess for actual diabetic foot complication, (b) assessment of footwear, (c) provision of patient education, and (d) initiating multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback. The primary outcome measured was appropriate referrals, defined as a referral to the specialty clinic that is ordered by the provider for individuals with a SWM tool score of 3 and a 'yes' for referral that has been documented by the provider in the EMR. Findings showed that the interventions improved appropriate referral ( $\chi^2(1) = 72.657$ ;  $p < .001$ ), as well as the secondary outcomes of provider foot assessment ( $\chi^2(1) = 93.209$ ;  $p < .001$ ) and patient follow-up compliance to the Podiatry clinic (PC) following referral ( $\chi^2(1) = 88.7014$ ;  $p < .001$ ).

## CHAPTER 1

### INTRODUCTION

#### Background

Diabetes mellitus (DM) is a chronic metabolic disease characterized by high blood glucose levels due to the body's inability to adequately produce or efficiently use insulin effectively (van Acker et al., 2014). With the increasing prevalence of obesity, population growth, aging, urbanization, and physical inactivity, the number of people with diabetes is increasing (van Acker et al., 2014).

Diabetic patients who have uncontrolled glucose levels are at a greater risk for the development of severe vascular complications. While these complications can affect multiple organs, one of the most common areas that can be affected are the feet (Boulton et al. 2008; Feng et al., 2011; van Acker et al., 2014; Wang et al., 2017). Risk factors for the worsening of DM and the emergence of foot ulcers are age, type and time of diagnosis, inadequate control of blood glucose, smoking, alcoholism, obesity, hypertension, a history of ulcers in the feet, non-traumatic amputation, poor health education, neuropathy, non-ulcerative calluses and injuries and the use of inappropriate footwear (Feitosa et al., 2016).

Diabetic foot neuropathy (DFN) is associated with a loss of sensation in the foot and an increased incidence of foot ulcers resulting in foot infection and even amputation in individuals with DM in the late stage (Wang et al., 2017). Patients who experience the loss of protective sensation (LOPS) are at a greater risk for having the inability to sense minor trauma, altered plantar pressure, and deformity of the foot leading to foot ulcers and lower extremity amputations (LEA) (Feng et al., 2011).

Occurring in approximately 15% of patients who are diagnosed with diabetes, diabetic foot ulcer (DFU) is defined as an open sore or wound that is commonly located on the sole of the foot (Wang et al., 2017). Pressure plays a central role in the development of DFU.

Pressure results from the mechanical loading of the feet when the individual engages in activities such as walking and standing, exposing the plantar surface of the feet to reaction forces that act upon the foot tissue, causing compression and sometimes shear stress (Martins de Oliverira, A., & Moore, Z., 2015).

The 5.07/10g Semmes-Weinstein monofilament (SWM) examination is the gold standard quantitative sensory test that is noninvasive, inexpensive, rapid, and easy to use for diabetic peripheral neuropathy (DPN) screening that uses a single point of touch pressure to identify patients at higher risk for ulceration and amputation (Feitosa et al., 2016 & Feng et al., 2011). The methods for performing the SWM exam vary greatly, with differences in the number of sites and the threshold for defining the loss of sensation. When using SWM exam testing, foot assessment locations for use by health care providers include the plantar aspects of the great toe, the third and fifth metatarsals. Use of these sites maximizes the sensitivity and specificity of the test diagnosing DPN (Feng et al., 2011).

### **Data from the Literature Supporting Need for the Project**

The World Health Organization (WHO) estimates that the global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014 (WHO, 2018). In 2016, 1.6 million deaths were directly caused by diabetes (NCD Risk Factor Collaboration, 2017). Within this large diabetic population, 30% of patients aged 40 years or older have impaired sensation of the feet (Feng et al., 2011) making the lower limbs more vulnerable to the appearance of ulcers in patients who are diagnosed with DM (Feitosa et al., 2016). Every 20 seconds, a limb is amputated somewhere in the world as a result of diabetes with diabetes contributing to approximately 80% of the 120,000 non-traumatic amputations performed yearly in the United States (US) (Formosa et al., 2016). Patients who have DFUs are observed to be suffering from reduced quality of life (QOL) in terms of pain, time lost from work, and reduction in social activities leading to social isolation and loneliness (van Acker et al., 2014). One of the obstacles for preventing diabetic foot is the lack of examinations of the feet by health care

providers (HPCs) (Feitosa et al., 2016). It is theorized that the implementation of a structured diabetes foot screening program could achieve a 75% reduction in amputation rates (Formosa et al., 2016).

Early recognition and appropriate management of neuropathy in people with diabetes is important (American Diabetes Association (ADA), 2019; Boulton et al., 2008; Feitosa et al., 2016 & Formosa et al., 2016). The ADA recommends that HPCs conduct an annual comprehensive diabetic foot exam for diabetic patients to assist in identifying diabetic patients at risk for diabetic foot complication (ADA, 2018). Incorporating diabetic foot assessment into primary care will assist in early identification of risk for potential diabetic foot complication (Boulton et al., 2008).

#### **Data from the Clinical Agency Supporting Need for the Project**

The clinical site for this evidence-based practice (EBP) project is a large, busy, urban inner-city outpatient adult general medicine clinic that is an extension of a large community public teaching facility in the Midwest. Key stakeholders of this EBP project include the department administrative staff, senior leadership, eight team physician clinicians, two team nurse practitioner clinicians, four team medical assistants, two team registered nurses, and one team clerk. As a result of the Patient Protection and Affordable Care Act (ACA), many of the patients who receive clinical services via this EBP project site are covered through state and federal insurance subsidy programs and rarely incur out of pocket expenses.

On average, this clinic provides outpatient general medicine primary care services to approximately 350 patients per day. In 2018, of the approximate 59,000 patients who received services, the internal census record database identified 18,221 of them as being diagnosed with DM. Of this total, greater than 40% of these patients had a serum hemoglobin A1C (Hgb A1C) greater than 9%. Excluding those being co-managed by a specialty clinic podiatry or diabetes clinic less than 20% of these identified patients seen in the outpatient general medicine clinic setting had a documented clinical foot exam in the electronic medical record (EMR) through use

of the organization's computer software; Context Message Audience Purpose Product (CMAPP) (2018). This clinic setting was appropriate for this EBP project as it provided a large diabetic patient population which lacked a structured diabetic foot program in the primary care setting.

At the EBP clinical site, improving the assessment of DFN by primary care providers (PCPs) in the general medicine clinic has been identified as an organizational goal. As an advanced practice nurse (APN) in the general medicine clinic, the PL provides diabetes care to a vast number of patients at the EBP project clinical site. Recently the PL was invited to become a member of the Healthcare Effectiveness Data and Information Set (HEDIS) workgroup at the EBP project clinical site. This data set is a widely used set of standardized performance measures designed to provide purchasers and consumers with information they need for reliable comparison of Health plan performance is developed and maintained by the National Committee of Quality Assurance (NCQA). Analysis of HEDIS data helps to identify gaps in care, particularly preventative care to important and chronic populations such as those with DM (CMS, 2017).

Weekly, the PL attends and actively participates in organizational sponsored HEDIS meetings where the current focus is on improving diabetic patient foot care. In alignment with senior leadership's vision to implement diabetic foot care into the primary care setting and in response to the organization's priority of identifying and implementing best practice for diabetic foot care into primary care, the PL decided to focus her EBP project on the implementation of diabetic foot care. Given the size of the project site clinic location and volume of diabetic patients who receive service daily, participants of this EBP project will be limited to Team A clinicians and ancillary staff at the PL's place of employment in the general medicine clinic (GMC).

At the clinical site, the PL observed multiple instances when patients who have a diagnosis of DM (controlled and uncontrolled) received health care in the primary care setting that did not include a diabetic foot assessment, provision of provider referral to foot care

services, provision of a verbal or hardcopy foot care education information, and/or the inquiry of whether foot care services had been rendered at an outside facility within the last 12 calendar months. To circumvent diabetic foot assessment, it was determined that PCPs were simply referring patients to podiatry via the EMR without providing a baseline foot risk assessment to determine whether the referral was appropriate.

Feedback from senior leadership at the weekly HEDIS meetings, biweekly quality improvement (QI) meetings, and quarterly division meetings show a tremendous current backlog in the availability of podiatry clinic (PC) appointments for patients with identified need for specialty consultation and an overwhelmed PC staff that is unable to safely, efficiently or effectively provide care to the massive volume of patients backlogged in the podiatry referral EMR que. Time constraint was the most common reason given for not providing foot assessment during the clinical visit encounter. This inappropriate use of the referral system sparked the urgent need for organizational leadership to become involved in improving the workflow and provider service standards for diabetic patient care delivery.

### **Purpose of the Evidence-Based Practice Project**

The purpose of this EBP project is to implement provider use of best practice recommendations for the assessment of risk and actual diabetic foot complication for adult diabetic patients seen in the primary care setting. The use of identified evidence-based strategies will allow for the assessment of risk to reduce or prevent complications and provision of early diabetic foot care intervention to improve diabetic foot care outcomes.

### **PICOT Question**

Specifically, this project will address the following PICOT question; "In adult diabetic patients ages 18-74 seen in the primary care setting, does a multi-faceted intervention, compared to previous clinic foot care practices, result in referrals that are more appropriate, improved provider assessment, and increased patient compliance with follow-up appointments over a 12-week period?" The evidence-based multi-faceted intervention included: (a)

implementing provider history and foot physical assessment including the use of the SWM tool to assess for actual diabetic foot complication, (b) assessing of footwear, (c) providing patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback.

### **Significance of the EBP Project**

Patients who are diagnosed with DM provide 99% of their own care; however, foot self-care is often not practiced (Sharoni, et al., 2015). Diabetic foot complications are a common cause of non-traumatic limb amputations leading to disability (van Acker et al., 2014). One of the most common complications of DM is DPN, which is associated with the loss of sensation in the foot and increased incidence of foot ulcers (Wang et al., 2017). Every year, approximately 4 million people develop a new diabetic foot ulcer. Individuals who live in developed countries use 12-15% of health care resources for diabetes, while individuals in developing countries use nearly 40% (van Acker et al., 2014). Patients who are diagnosed with diabetes generally receive follow-up visits at regularly scheduled intervals with their PCP; however, these visits seldom included diabetic foot risk assessment screening. Multidisciplinary teams are best suited to provide care for people with chronic conditions such as diabetes and to facilitate patient self-care management (ADA, 2019).

The significance of this EBP project is embedded in the urgent need identified by senior leadership at the project clinical site to mitigate risk associated with diabetic foot complication. Incorporating the provision of evidence-based PCP diabetic foot assessment into primary care visits will reduce the risk for complication, increase early detection and intervention, and promote best patient outcomes. Identifying and implementing best practice recommendations for PCP diabetic foot risk assessment addresses the clinical problem by impacting and improving diabetic foot clinical care delivery practices, increasing patient QOL, decreasing the financial burden associated with diabetic foot complication, reducing lengths of hospitalizations,

and providing systematic workflow by which PCPs can deliver consistent high quality, high level foot care to diabetic patients seen in the primary care setting.

The diagnosis of DM can potentially cause nerve damage, circulation complications and infections. This EBP project is important because it identifies the importance of provider use of best practice recommendations for performing diabetic foot risk assessment in the primary care setting. This will aid in detecting DFC sooner and may prevent foot complication progression. This project addresses the clinical problem by (a) implementing a provider history and foot physical assessment to include the use of the (SWM) tool to assess actual diabetic foot complication, (b) assessing footwear, (c) providing patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback.

## CHAPTER 2

### EBP MODEL AND REVIEW OF LITERATURE

#### Evidence-based Practice Model

In this chapter, the EBP model and current evidence from the literature about the implementation of provider assessment of actual diabetic foot complication in the primary care setting is described. It is imperative for the doctor of nursing practice (DNP) prepared nurse to effectively evaluate and utilize evidence from the literature to guide clinical practice changes that will promote the best possible patient outcomes. The Iowa Model Revised: Evidence Based Practice to promote Excellence in Healthcare (Iowa Model Collaborative, 2017) and clinical practice guidelines (CPG's) were used as a framework to build a solid foundation to support the adoption and implementation of best practice at the project clinical site.

The PICOT question guiding this EBP project was; "In adult diabetic patients ages 18-74 seen in the primary care setting, does a multi-faceted intervention, compared to previous clinic foot care practices, result in referrals that are more appropriate, improved provider assessment, and increased patient compliance with follow-up appointments over a 12-week period?" The evidence-based multi-faceted intervention included: (a) implementing provider history and foot physical assessment including the use of the SWM tool to assess for actual diabetic foot complication, (b) assessing of footwear, (c) providing patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback. To effectively answer this question, PL performed a comprehensive review of the literature, appraisal and synthesis of the evidence, determined best practice, assessed the feasibility for use in the clinical setting, ascertained stakeholder engagement, and planned a systematic approach to the implementation of practice change.

### **Overview of EBP Model**

The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) was used to guide the implementation of this EBP project. The Iowa Model was based on Rogers (1983) Theory of Diffusion of Innovations, and was an outgrowth of the Quality Assurance Model Using Research (Watson et al., 1987). The model, which was originally entitled, "The Iowa Model of Research Based Practice to Promote Quality Care," was first developed and implemented in 1994 at the University of Iowa Hospitals and Clinics to serve as a guide for nurses and other health care providers to use research findings for improvement of patient care (Titler et al., 2001). The Iowa Model focuses on collaboration within an organization to research other types of evidence (Titler et al., 2001).

Over the years, nurses have used the original Iowa Model (Titler et al., 1994) to identify areas in clinical practice where problem and knowledge focused triggers existed that could be addressed through synthesis and application of research findings (Titler et al., 2001). Feedback from the nurses who used the model, as well as developments in the health care market, served as the catalyst for the 1998 revision of the Iowa Model that was later published in 2001 as The Iowa Model of Evidenced Based Practice to Promote Quality Care (Titler et al., 2001).

Within the practice setting, there is an increasing challenge to provide clearly measurable care of the highest quality that is evidenced based (Doody & Doody, 2017). Since the last revision of the Iowa Model (Iowa Model Collaborative, 2017), dramatic changes have evolved in health care including an explosion of synthesized evidence, national and international initiatives promoting adoption of EBP, enhanced interprofessional collaboration, widespread use of electronic data, emergence of implementation of science, pay for performance and enhanced patient engagement (Iowa Model Collaborative, 2017). In 2012, the Iowa Model Collaborative (Iowa Model Collaborative, 2017) was formed to assess the need for model revision. All prior authors and key stakeholders were invited to participate in the Iowa Model Collaborative (Iowa Model Collaborative, 2017). The group convened to revise and validate the Iowa Model through

the use of a systematic, multiphase process of collecting and analyzing user suggestions which were used in the development of the Iowa Model Revised (Iowa Collaborative Model, 2017).

The Iowa Model-Revised: Evidence Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) provided a streamlined step by step approach, thereby making it easier for clinicians to use. Results of the revision included nine problem and knowledge focused triggers (Iowa Model Collaborative, 2017). Steps for the revised model include: (a) identifying triggering issues and opportunities, (b) stating the question or purpose, (c) determining organizational project topic priority, (e) forming a team, (f) assembling, (g) appraising and (h) synthesizing a body of evidence, (i) determining if there is sufficient evidence, (j) designing and piloting the practice change, (k) determining if the change is appropriate for adoption, (l) integrating and (m) sustaining the practice change, and (n) disseminating the results (Iowa Collaborative, 2017). Though simplified, the revised model preserved the analytical and critical thinking skill set of the clinician as in the original model. The model is adaptable for novice to expert users and has been used in over 23 countries in a variety of settings (Iowa Collaborative Model, 2017).

### **Application of EBP Model to DNP Project**

Currently, there is a lack of standardized diabetic foot risk assessment by providers in the primary care setting. The Iowa Model Revised (Iowa Collaborative Model, 2017) was used to guide the implementation of SWM use by PCPs to assess diabetic patient risk for the development of diabetic foot complication. The following summary describes how the Iowa Model Revised (Iowa Collaborative Model, 2017) was used to address the clinical problem identified in this project.

**Identifying the triggering issues and opportunities.** Step one of the Iowa Model Revised is identifying the triggering issues and opportunities (Iowa Collaborative Model, 2017). Problem and knowledge focused triggers are catalysts for nurses to think critically about clinical and operational efficiency and effectiveness and thus seek scientific knowledge for use in

decision making (Titler et al., 2001). The trigger for this EBP project was the identified need for diabetic patients being seen in primary care to receive diabetic foot risk assessment to assess patients risk for the development of diabetic foot complication. Organizational leadership determined that PCPs of this facility were in a strategic position to perform and document diabetic foot assessments for diabetic patients seen in the primary care setting to promote early referral and intervention to specialty services and decrease the overall risk for diabetic foot complication.

**Stating the question or purpose.** Step two of the Iowa Model Revised is stating the question or purpose. Formally stating the purpose enables a more focused approach to synthesizing the body of evidence and better informs the next decision points (Iowa Collaborative Model, 2017). This change was implemented into the revised Iowa model as a result of feedback from users of the model. Users of this model have applied the PICOT format as the question when using this model (Iowa Collaborative Model, 2017). Utilizing the EBP clinical question for this project in the Iowa Model Revised format would read as follows; “In adult diabetic patients ages 18-74 seen in the primary care setting, does a multi-faceted intervention, compared to previous clinic foot care practices, result in referrals that are more appropriate, improved provider assessment, and increased patient compliance with follow-up appointments over a 12-week period?” The evidence-based multi-faceted intervention included: (a) implementing provider history and foot physical assessment including the use of the Semmes Weinstein Monofilament (SWM) tool to assess for actual diabetic foot complication, (b) assessing of footwear, (c) providing patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback.

**Priority of the topic.** Step three of the Iowa Model Revised is very important because determining the priority of project topic as it relates to the direction of the organization will impact the success or failure of the project outcome (Iowa Collaborative Model, 2017). Previous to the selection of this project topic, this PL experienced first-hand how the lack of

organizational support could cause a seemingly good project topic to lose momentum and ultimately not come to fruition. This EBP project topic was identified by the organization as a priority and was determined to be a good fit with the interventions that are being implemented for diabetic patients in the department of general medicine in primary care at the project facility location. Selecting a project that was congruent with organizational goals has come with the full support of both the administrative and ancillary clinic support staff.

**Forming a team.** Step four of the Iowa Model Revised is the formation of a team (Iowa Collaborative Model, 2017). For this EBP project to be successful, a collaborative team approach to the delivery and implementation of diabetic foot assessment was necessary. Selection of team members requires attention to inter professional involvement, as well as skill sets needed to plan, conduct and evaluate the project (Iowa Collaborative Model, 2017). This EBP project team consisted of 10 team-based clinic clinicians, 1 clerk, 4 medical assistants, 2 registered nurses, and podiatry providers. Collaboratively, this team worked together to pilot and implement this EBP clinical project.

**Assemble, appraise and synthesize body of evidence.** Step five of the Iowa Model Revised is the assembly, appraisal, and synthesis of evidence. It is important to conduct a systematic search of the literature and be involved in evaluating the evidence to guide subsequent work (Iowa Collaborative Model, 2017). A thorough search of multiple databases was conducted by the PL to obtain literature to identify and support best practice to address the clinical question. Evidence obtained was then critically appraised by the PL for quality and level to determine usability for this EBP project. Literature of the highest-level standard and quality was then synthesized by the PL to ascertain the appropriate intervention to guide the implementation of best practice for this EBP project.

**Determining if there is enough evidence.** Step six of the Iowa Model Revised is to determine whether sufficient evidence exists to continue forward with the project (Iowa Collaborative Model, 2017). Synthesis of the assembled literature showed sufficient evidence

exists to address the clinical question. It was critical for the PL to determine the following: (a) the consistency of findings across studies, (b) the type and quality of studies, (c) the clinical relevance of the findings for practice, (d) the number of studies with sample characteristics similar to those which the findings are to be applied, (e) the feasibility of the findings for use in practice, and (f) the risk: benefit ratio (Titler et al., 2001). For this EBP project, while the literature supported the existence of sufficient evidence to support and guide practice change, the PL had to institute minor modifications in order to make these changes conducive to the project site setting,

**Designing and piloting the practice change.** Step seven of the Iowa Model Revised (Iowa Collaborative Model, 2017) was to design and pilot the practice change. Prior to beginning implementation of the practice change, the PL reviewed the literature and collected baseline data from the project clinical site. Piloting a research-based change in the clinical setting takes the intervention away from the controlled environment of a research study and puts it into an environment where the results of extraneous variables influence the results (Titler et al., 2001). The clinical setting for this EBP project involved a team approach to pilot the implementation of the primary care provider by: (a) obtaining a history and foot physical assessment, including provider use of the SWM tool for the assessment of actual diabetic foot complication, (b) assessment of footwear, (c) provision of patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow and providing ongoing feedback. Piloting the implementation of a new practice process on a smaller scale will allow the opportunity for the organization and PL to determine feasibility and effectiveness of implementing a guideline into the selected clinical settings (Titler et al., 2001).

Each single use disposable monofilament unit is estimated to cost \$1.25. The expense budget for the bulk purchase cost of stocking the SWM tool in the department of primary care for the organization was calculated by senior leadership and has been financially assumed by

the organization. Project design details regarding training, patient education, workflow, and ongoing feedback were planned during this phase of the implementation process.

After completing a screening tool, it was determined that university IRB approval of this project was not necessary at the university or the EBP project site. Post pilot data was actively being collected for analysis by the PL and leadership to determine possible need for project modification and or readiness for implementation of project interventions on a larger scale clinic wide. In this step, the multi-faceted intervention was piloted in the clinical setting.

**Determining project appropriateness for adoption.** Step eight of the Iowa Model Revised (Iowa Collaborative Model, 2017) is to determine whether the project is appropriate for adoption in practice. Scholarly evaluation of pilot data will guide the decision of determining whether the practice change worked, whether the implementation plan was effective and if rollout to other areas would be beneficial (Iowa Model Collaborative, 2017). After the EBP project has been piloted, a decision will be made about adopting the practice for all appropriate patient populations (Titler et al., 2001). The EBP PL will continue to work closely with organizational leadership to include ongoing quality improvement monitoring and feedback to determine the need to support continued project change practice, need for project modification or recommendation for renewed review of the research literature.

**Integrating and sustaining the project change.** Step nine of the Iowa Model Revised (Iowa Collaborative Model, 2017) is to integrate and sustain the project change. Integration of this EBP project change into practice for the identified diabetic patient population at this EBP project clinic site would be considered a favorable outcome of the pilot phase for this EBP project. The ability to link the multi-faceted approach to the provision of diabetic foot care to include provider foot risk assessment including use of the SWM tool, assessment of footwear, provision of patient and clinician education, the planning a clinical workflow and the provision of ongoing feedback by the PL to the clinicians was a solid starting point by which this PL plans to approach leadership for support in sustaining the interventions that have been implemented to

support the continued improvement of diabetic foot care outcomes at this EBP project clinical site. Key indicators to monitor include structure (e.g. staffing, available equipment), process (ie. knowledge attitudes and practices), and outcomes including balancing measures (Scoville, Little, Rakover, Luther, Mate, 2016).

**Disseminating the result.** The final step to the Iowa Model Revised (Iowa Collaborative Model, 2017) is the dissemination of the results. The dissemination of results step in the Iowa Model Revised remains unchanged from the original Iowa Model of Research Based Practice to Promote Quality Care. Dissemination of results provides clinicians and organizations a pathway to share knowledge, research findings and results of the implementation of evidence based interventions. Dissemination can strategically occur via the use of a variety of different modalities.

Internal dissemination of results is important as it provides a way for the organization and PL to provide feedback and to share outcomes with clinical staff, patients and other stakeholders. This can ultimately create an environment of added support, continued dedication and commitment to the provision of high quality care by all involved. Site leadership and the PL's site advisor will collectively determine the details on whether the PL will formally present outcome details about the project.

External dissemination is equally as important because it allows results to be shared locally, regionally, nationally and internationally on a larger scale. External dissemination can best be facilitated through the application and result inclusion in publications, conferences, seminars, webinars and other large scaled shared educational platforms. Oral poster presentations about this EBP project were made at Valparaiso University as a course requirement. This dissemination forum allowed the PL to share project outcomes with faculty, academic peers, family, and friends.

### **Strengths and Limitations of EBP Model for DNP Project**

Use of the Iowa Model Revised (Iowa Model Collaborative, 2017) provides a systematic framework which allows clinicians to focus on knowledge and problem focused triggers, leading staff to question current nursing practices and whether care can be improved through the use of current research findings (Titler, 2006). At the EBP project site, using the model, (Iowa Collaborative Model, 2017) assisted in improving the frequency of provider foot risk assessments, appropriateness of referrals, and patient follow-up to the PC as scheduled by providing a systematic method of implementing best practice recommendations for implementing a multifaceted, multidisciplinary approach to the provision of diabetic foot care in the primary care setting.

A major strength of the model is that it was developed by clinicians for clinician use which makes feasibility of use in the clinical setting at the EBP project site more favorable. Following the structural framework of the Iowa Model Revised (Iowa Model Collaborative, 2017) the PL created a step by step algorithmic workflow for Team A can clinician use. The model flowchart includes feedback loops for clinicians to follow in addressing the clinical question for this EBP project. Use of the model will work to promote consistency in practice that can assist in the development of guidelines and protocols establishing a standard of care for foot risk assessment if adopted by the organization.

Another strength of the Iowa Model Revised (Iowa Model Collaborative, 2017) is the inclusion and provision of the pilot phase. The EBP project clinic site is serving as the pilot site for the implementation of diabetic foot risk assessment into primary care for the organization. The Iowa Model Revised (Iowa Collaborative Model, 2017) is being used as a guide to support this vision. Collaborative use of the model and best practice recommendations will promote best patient outcomes.

One identified limitation of the use of the Iowa Model Revised (Iowa Collaborative Model, 2017) is that it is not designed for individual clinician use in addressing a clinical problem. The step by step structure of the model is not conducive to the individual clinician being able to

competently pilot or implement a proposed evidence based intervention of best practice change that has been devised through only individual efforts. This limitation makes it necessary for the PL to depend on the cooperation of all participants in order for implementation to have a viable chance at being successful. Step four of the Iowa Model Revised (Iowa Collaborative Model, 2017) is the formation of a team. The composition of the team should be directed by the chosen topic and should include all interested stakeholders (Doody & Doody, 2011). Leadership support made team participation and workflow modification a feasible and favorable transition for all participants.

### **Literature Search**

Evidence based practice has been shown to improve patient care and outcomes (Black, A., Balneaves, L., Garossino, C., Puyat, J., Qian, H., 2014) and is therefore critically important to the current and future profession of nursing. Utilization of research based knowledge provides nurses the opportunity to consistently deliver safe, efficient, high quality care. Step five of the Iowa Model Revised (Iowa Model Collaborative, 2017) speaks to the importance of nurses assembling, appraising, and synthesizing the evidence found in the literature in an effort to determine and implement best practice. To achieve best practice, it is vital for the doctorally prepared to perform an exhaustive review of the current literature.

### **Sources Examined for Relevant Evidence**

Conducting a thorough systematic search of the literature is a very important step in the Iowa Model Revised (Iowa Model Collaborative, 2017) as it will allow nurses to systematically assemble, appraise and synthesize the evidence that is being reviewed for best practice recommendations to address the clinical questioning being proposed. For this EBP project, this PL was in search of high level, high quality evidence from sources such as systematic reviews, meta-analysis, randomized control trials (RCTs) and clinical practice guidelines (CPGs). The PL also utilized a search method referred to as citation chasing which entailed the PL locating a

piece of evidence that was cited in another piece of evidence that was yielded as part of the original search but is relevant to the project topic being researched.

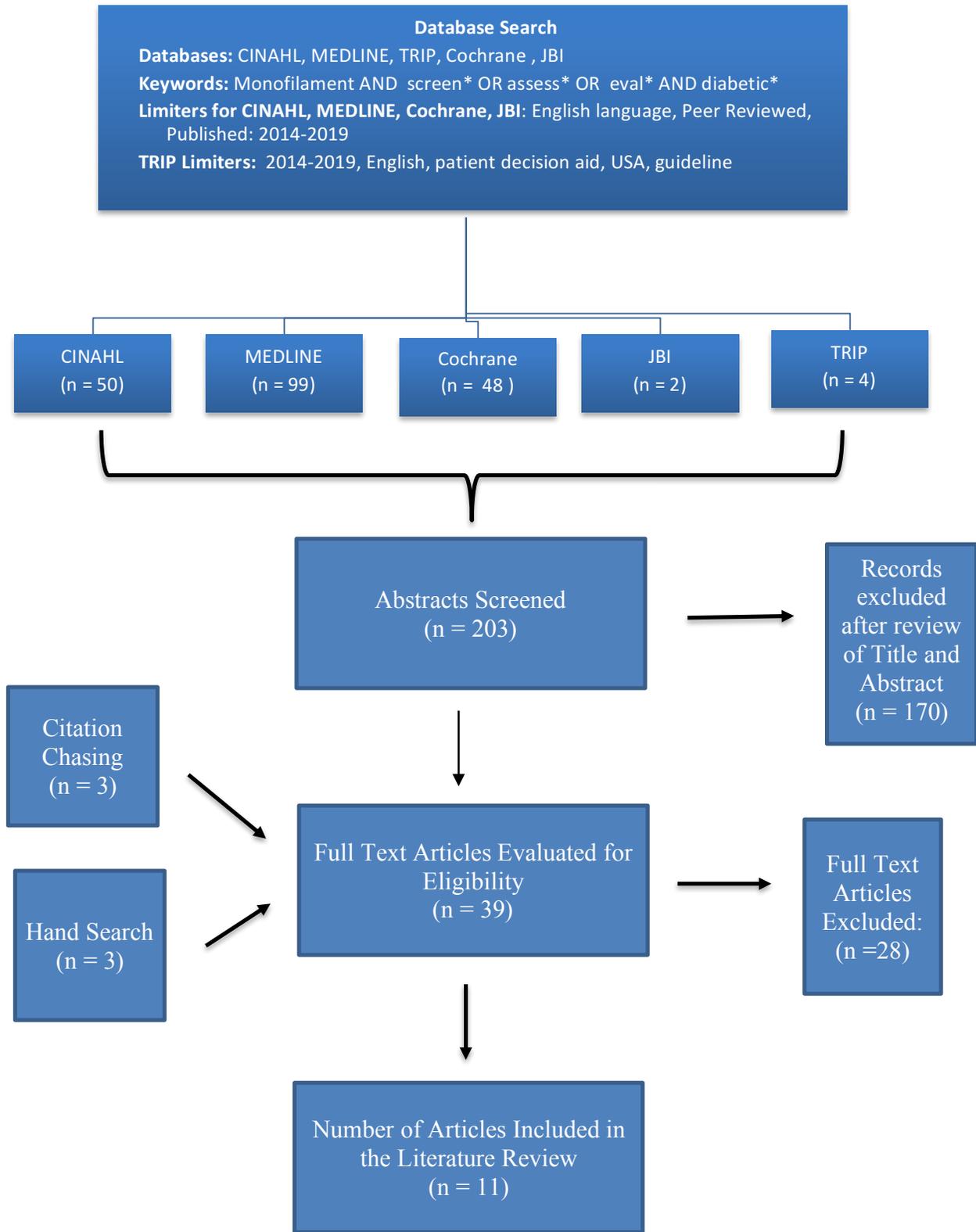
**Search engines and keywords.** To obtain the best, most relevant evidence to answer the PICOT question, under the guidance of the Research Services Librarian, this PL performed a thorough review of current literature. The goal of this literature search was to gather high level, high quality evidence that had best practice for the implementation of this EBP project. Five databases were thoroughly explored: (a) Cumulative Index to Nursing and Allied Health Literature (CINAHL), (b) MEDLINE, (c) Cochrane, (d) Joanna Briggs Institute (JBI), and (e); Turning Research into Practice (TRIP). Duplicate pieces of evidence were eliminated. The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) process is summarized in Figure 2.1. Variations of search terms included monofilament, screen, assess, eval\*, and diabetic. Strategies involving proper Boolean and truncation strategies were implemented.

**Inclusion and exclusion criteria.** To narrow the database search results for articles that were relevant to the EBP project topic, inclusion and exclusion criteria were set by the PL. Inclusion criteria included literature published between 2014-2019, scholarly and peer reviewed journals and literature written in the English language. Exclusion criteria included articles that were published prior to 2014, literature that was not published in English, patients who experienced bilateral lower extremity amputation, articles involving children or patients who experienced other comorbidities with diabetes. The CINAHL database search yielded 50 pieces of evidence. The initial search of the CINAHL database utilized keywords such as monofilament and diabetic\* with the Boolean operator AND between the two words. This search yielded 55 pieces of evidence. The second search of the CINAHL database used keywords to include: monofilament, screen\* and diabetic\* with the Boolean operator AND between each of the three words. This search yielded 17 pieces of evidence. The third CINAHL database search used keywords to include: monofilament, screen\*, assess\* and diabetic\*. The Boolean operator

AND was placed between monofilament AND screen\* and Boolean operator OR was placed between screen\* OR assess\*. The asterisk was used for truncation after the word screen\* OR assess\*. The Boolean operator AND was added between screen\* OR assess\* AND diabetic\*. This search yielded 38 pieces of evidence. The final search of the CINAHL database included keywords: monofilament, screen\*, assess\*, eval\* and diabetic\*. The Boolean operators AND and OR were placed between monofilament AND screen\* and Boolean operator OR was placed between screen\* OR assess\*. The asterisk was used for truncation after the word screen\* OR assess\*. The Boolean operator AND was added between screen\* OR assess\* AND diabetic\*. This search yielded 38 pieces of evidence. The final search of the CINAHL database included keywords: monofilament, screen\*, assess\*, eval\* and diabetic\*. The Boolean operators AND and OR were placed between monofilament AND screen\* OR assess\* OR eval\* AND diabetic\* with use of the asterisk truncation. This result yielded 50 pieces of evidence. Limiters of the CINAHL database search included evidence published between 2014-2019, English language, scholarly and peer reviewed journals.

The MEDLINE database was searched and yielded 99 pieces of evidence. The initial search of the MEDLINE database utilized the keywords to include: monofilament and diabetic\* with the Boolean operator AND between the two words. This search yielded 117 pieces of evidence. The second search of the MEDLINE database used keywords to include: monofilament, screen\* and diabetic\* with the Boolean operator AND between each of the three words. This search yielded 46 pieces of evidence. The third MEDLINE database search used keywords to include: monofilament, screen\*, assess\* and diabetic\*. The Boolean operator AND was placed between monofilament AND screen\* and Boolean operator OR was placed between screen\* OR assess\*. The asterisk was used for truncation after the word screen\* OR assess\*. The Boolean operator AND was added between screen\* OR assess\* AND diabetic\*. This search yielded 78 pieces of evidence. The final search of the MEDLINE database included keywords: monofilament, screen\*, assess\*, eval\* and diabetic\*. The Boolean operators AND

Figure 2.1 PRISMA flow chart of Literature Review



and OR were placed between monofilament AND screen\* OR assess\* OR eval\* AND diabetic\* with use of the asterisk truncation. This result yielded 99 pieces of evidence. Limiters used when searching the MEDLINE database included evidence published between 2014-2019 and English language. and OR were placed between monofilament AND screen\* OR assess\* OR eval\* AND diabetic\* with use of the asterisk truncation. This result yielded 99 pieces of evidence. Limiters used when searching the MEDLINE database included evidence published between 2014-2019 and English language.

The Cochrane database was searched and yielded 0 systematic reviews, 0 protocols, 48 trials, 0 clinical trials despite the use of a simpler search strategy. The initial Cochrane database search used keywords to include monofilament and diabetic\*. The Boolean operator AND was used between the two words. This search yielded 0 systematic reviews, 0 protocols, 0 Clinical answers and 25 trials. The second search of the Cochrane database yielded 0 systematic reviews, 0 protocols, 0 Clinical Answers and 25 trials. Keywords for this search included monofilament, screen\* and diabetic\* The Boolean operator AND was used between each word. The third Cochrane database search yielded 0 systematic reviews, 0 protocols, 0 clinical answers and 8 trials. Keywords for this third search included monofilament and “diabetic foot”. Boolean operator AND was placed between the two words. Quotations were placed around keywords with two or more word phrases. The final Cochrane database search yielded 0 systematic reviews, 0 protocols, 48 clinical answers and 8 trials. Keywords for this final search included monofilament, screen\* and “diabetic foot”. Boolean operator AND was used between each word, an asterisk truncation was used after the word screen\* and quotation marks were placed around keywords with 2 or more phrases. Limiters of the Cochrane database included evidence published between Jan 2014-June 2019, Systematic Reviews, Protocols, Clinical Answers and Trials.

The Joanna Briggs Institute (JBI) database yielded 2 pieces of evidence. The JBI database was searched and yielded 2 systematic reviews despite the use of a simpler search

strategy. The initial JBI database search used keywords to include monofilament and diabetic\*. The Boolean operator AND was used between the two words. This search yielded 2 systematic. The second search of the JBI database yielded 2 systematic reviews. Keywords for this search included monofilament, screen\* and diabetic\*. The Boolean operator AND was used between each word. The third JBI database search yielded 2 systematic reviews. Keywords for this third search included monofilament and "diabetic foot". Boolean operator AND was placed between the two words. Quotations were placed around keywords with two or more word phrases. The final JBI database search yielded 2 systematic reviews. Keywords for this final search included monofilament, screen\* and "diabetic foot". Boolean operator AND was used between each word, and an asterisk truncation was used after the word screen\* and quotation marks were placed around keywords with 2 or more phrases. Limiters when searching the JBI database included evidence published between 2014-Current and Systematic Reviews.

The Turning Research into Practice (TRIP) database was searched and yielded 4 pieces of evidence. The initial search of the TRIP database used the following keywords: monofilament and diabetic\* with the Boolean operator AND between the two words. This search yielded 5 pieces of evidence. The second search of the TRIP database used keywords to include: monofilament, screen\* and diabetic\* with the Boolean operator AND between each of the three words. This search yielded 3 pieces of evidence. The third TRIP database search used keywords to include: monofilament, screen\*, assess\* and diabetic\*. The Boolean operator AND was placed between monofilament AND screen\* and Boolean operator OR was placed between screen\* OR assess\*. The asterisk was used for truncation after the word screen\* OR assess\*. The Boolean operator AND was added between screen\* OR assess\* AND diabetic\*. This search yielded 349 pieces of evidence. The final search of the TRIP database included keywords: monofilament, screen\*, assess\*, eval\* and diabetic\*. The Boolean operators AND and OR were placed between monofilament AND screen\* OR assess\* OR eval\* AND diabetic\* with use of the asterisk truncation. This result yielded 4 pieces of evidence. Limiters when

searching the TRIP database included evidence published between 2014-2019, English language, guidelines, USA and patient decision aids.

The PL was able to obtain 3 additional pieces of evidence via the process of citation chasing. Citation chasing refers to the process of retracing the research of an author. The method of using cited references and bibliographies to guide your search process which prompts you to read and engage with research that is already in conversation with researchers in the discipline (University of Illinois, 2017). The method of using references to guide your literature search process allows for the potential opportunity to locate additional literature relevant to the search. The evidence obtained as a result of citation chasing was reviewed, appraised and retained for use in this literature review. Though outdated (greater than 5 years old) the PL elected to retain these 3 pieces of relevant evidence because of the high-quality rating each article received from an appraisal.

In addition to the database search, this PL performed a hand search of the literature which resulted in 3 articles. Hand searching is a manual method of scanning journals from cover to cover, page by page for relevant articles in case they are missed during indexing (Rutgers University). The three hand searched articles were reviewed, appraised and retained for use in this literature review. Database search results for this project are detailed in Table 2.1.

### **Levels of Evidence**

The Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Research and Non-Research Evidence Appraisal Tool (Dang & Dearholt, 2017) was used to rate the level of evidence for this EBP project. When appraising individual research studies, two major components come into play: (a) study design (level), and (b) study quality (methods and execution). Particular attention is given to study limitations (Dang & Dearholt, 2017). Table 2.1 categorically presents the 11 pieces of final evidence used to support the implementation of this EBP project. The evidence table in Appendix A, provides details regarding article type and content.

### **Appraisal of Relevant Evidence**

It is critical for the DNP prepared nurse to competently perform an appraisal of the evidence that is being considered for inclusion to support a practice change. This PL utilized the JHNEBP tool (Dang & Dearholt, 2017) to conduct the quality appraisal of the 11 pieces of evidence. This tool was selected for the ease of use of its step by step approach to appraise the evidence. The tool can be used by an individual clinician or by a clinical team.

The JHNEBP tool (Dang & Dearholt, 2017) has a quality grading system to identify the quality of evidence. The grade of A denotes high quality evidence that has consistent and generalizable results, a sufficient sample size for the study design, adequate control, definitive conclusions, and consistent recommendations based on comprehensive literature review that includes thorough reference in scientific evidence. The grade of B denotes evidence that is of good quality and described as having reasonably consistent results, sufficient sample size for the study design, and some control and fairly definitive conclusions, reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence. The grade of C denotes low quality evidence or evidence that has major flaws or consists of little evidence with inconsistent results., insufficient sample size for the study design, and conclusions that cannot be drawn (Dang & Dearholt, 2017). The evidence for this literature review did not include any evidence that was rated as level C.

**Level I evidence.** Level I evidence, the highest in the ranking hierarchy, includes well-designed RCTs and systematic reviews of RCTs with or without meta-analysis (Dang & Dearholt, 2017). A total of four sources of Level I evidence were utilized for this literature review and included: (a) one systematic review with meta-analysis (Adiewere et al., 2018) rated as quality A, (b) one screening guideline (Formosa et al., 2015) rated as quality B, and (c) two clinical guidelines (ADA,2018; ADA, 2019) which were both rated as B quality.

Table 2.1

*Database Search Results*

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Database	Evidence Yielded	Duplicates	Reviewed	Accepted
CINAHL	50	8	16	3
MEDLINE	99	7	19	1
Cochrane	48	2	3	0
JBI	2	1	1	1
TRIP	4	0	0	0
Citation Chase	3	0	3	3
Hand Search	3	0	3	3
Total	209	18	25	11

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**Level II evidence.** According to Dang and Dearholt (2017), Level II evidence includes quasi-experimental studies, explanatory mixed methods with only Level II quantitative studies, and systematic reviews of a combination of RCTs and quasi-experimental studies. The Level II evidence utilized for this literature review consisted of two systematic reviews (Feng et al., 2011; Sharoni et al., 2016). The quality ratings for each of these reviews were B (Good quality).

**Level III evidence.** Level III evidence includes quantitative non-experimental or explanatory mixed methods with only one level III quantitative studies, as well as exploratory, convergent, or multi-phasic mixed methods studies. Any systematic review that includes non-experimental studies also falls in this level. Additionally, qualitative studies are also Level III (Dang & Dearholt, 2017). Level III evidence included for this literature review consists of one systematic review and meta-analysis (Wang et al., 2017). The quality rating for this evidence was B (Good quality). The two systematic reviews (Martins de Oliveira & Moore, 2015; van Acker et al., 2014) each had a quality rating of A (high quality). The final piece of level III evidence was an integrative review (Feitosa et al., 2016) with a quality rating of B (Good quality).

**Level IV evidence.** Level IV evidence is defined as Consensus or position statements being similar to clinical practice guidelines (CPGs) in that they are systematically developed recommendations that may or may not be supported by research. CPGs are broad statements of best practice; are most often meant to guide members of a professional organization in decision making; and do not provide specific algorithms for practice. (Dang & Dearholt, 2017, p. 146)

The level IV evidence for this literature review consisted of a review report by the Task Force of Foot Care Interest Group of the American Diabetes Association (ADA, 2018), with endorsement by the American Association of Clinical Endocrinologists (Boulton et al., 2008). The quality rating for this evidence was B (Good quality) (Table 2.2)

### **Synthesis of Critically Appraised Literature**

In 2016, less than one third of diabetic patients in the United States received foot exams in the clinical setting by a PCP (CDC, 2017). This literature review provides the knowledge foundation necessary to strategically assist primary care providers in determining best practice for implementing foot assessment of diabetic patients seen in the primary care setting to assist in the reduction of risk of diabetic foot complication. To improve patient outcomes, a critical analysis and appraisal of strategies and assessment modalities identified in the literature will serve to guide the recommendation and implementation of best practice for this EBP project. Primary care providers should conduct an assessment, provide patient education and use a multidisciplinary approach.

#### **Assessment**

**History.** One of the obstacles for preventing diabetic foot is the lack of examinations of the feet in clinical practice (Feitosa et al., 2016). Taking a history is an important part of the assessment process. Most importantly, primary care providers should question patients about past DFU and amputations (ADA, 2019). It is also important for primary care providers to ask about patient use of tobacco (ADA, 2019; Boulton et al., 2008). Tobacco use is a risk factor that if modified can help to slow the effects of tissue hypoxia which contribute to poor healing and increased risk for amputation in diabetic patients (CDC, 2017).

**Physical exam.** While obtaining a patient's history is an important component of risk assessment, a patient cannot be fully assessed for risk for diabetic foot ulceration based on a history alone. A careful foot exam remains the key component to this process (ADA, 2019; Boulton et al., 2008; Formosa et al., 2016). A focused physical exam should be performed at least annually for all individuals who are diagnosed with diabetes (ADA, 2019; Formosa et al., 2016). These exams can be performed by primary care providers as well as diabetic specialists (ADA, 2018; Adiewere et al., 2018; van Acker et al., 2014). The physical exam should include a bilateral foot dermatologic, neurologic, vascular and musculoskeletal assessment. In addition,

Table 2.2

*Rating Hierarchy for Level of Research Evidence using the JHNEBP Appraisal Tool*

Author(s)	Level of Evidence	Quality of Evidence	Database
Adiewere et al. (2018)		A	Hand Search
American Diabetes Association (2018)	I	B	Citation Chase
Boulton et al. (2008)	IV	B	Citation Chase
American Diabetes (2019)	I	B	Citation Chase
Feitosa et al. (2016)	III	B	CINAHL
Feng et al. (2011)	II	B	CINAHL
Formosa et al. (2015)	I	B	CINAHL
Martins de Oliveira & Moore (2015)	III	A	JBI
Sharoni et al. (2015)	II	B	Hand Search
Wang et al. (2017)	III	B	MEDLINE
van Acker et al. (2014)	III	A	Hand Search

providers should perform bilateral foot inspection of footwear (Boulton et al., 2008; Martins de Oliveira & Moore, 2015; and Sharoni et al., 2016).

***Dermatologic assessment.*** The dermatologic examination should include the assessment of skin status: (a) color, (b) thickness, (c) dryness, and (d) cracking. The foot should be assessed for sweating, signs of infection (check between the toes for signs of fungal infection), ulceration, calluses, blistering and bleeding. Any identified abnormalities should be referred for additional diagnostic testing treatment, and or specialty assessment.

***Neuropathy assessment.*** Several studies show that early detection of DPN contributes to the prevention of foot ulcers and amputation (Boulton et al., 2008; Martins de Oliveria & Moore., 2015; van Acker et al., 2014; Wang et al.,2017). The gold standard for assessing the risk of neuropathy or LOPS involves using the SWM tool (ADA, 2019; Boulton et al., 2008; Feitosa et al., 2016). It has been determined that this tool is reliable for predicting both the absolute and relative risk for a diabetic patient to develop an ulcer (Feng et al., 2011; Wang et al., 2017). Recommendations for patient referral are based on the score achieved using the SWM (Table 2.3). Proper use of the SWM tool is described as follows.

Nylon monofilaments are constructed to buckle when a 10-g force is applied; loss of the ability to detect this pressure on the plantar surface of the foot has been associated with loss of large fiber nerve function. It is recommended that four sites (1<sup>st</sup>, 3<sup>rd</sup> and 5<sup>th</sup> metatarsal heads and plantar surface of the distal hallux) be tested on each foot. (Boulton et al., 2008, p.1680).

The 10-g monofilament single use monofilament should be used to conduct the foot risk assessment exam.

The patient should close their eyes while being tested. The sites of the foot may then be examined by asking the patient to respond “yes” or “no” when asked whether the monofilament is being applied to the particular site; the patient should

recognize the perception of pressure as well as identify the correct site. Areas of callous should always be avoided.” (Boulton et al., 2008, p. 1680).

While some studies were focused on a single approach method to address the issue of which tool is best suited for the screening of diabetic foot neuropathy (Feitosa et al., 2016; Feng et al., 2011; Wang et al., 2017), others considered alternatives for screening for DPN (ADA, 2019; Boulton et al., 2008; Formosa et al., 2015) which may serve to provide room for modification of screening methods as determined to be feasible in various clinical environments. For example, when the SWM tool is not available, one such option is the 24g x 0.75 angiocath (Feitosa et al., 2016). It has been shown that use of the angiocath is comparable in functionality to the monofilament tool to test peripheral sensitivity in the completion of a foot exam. Foot risk assessment that is conducted with the use of the angiocath is conducted in the same stepwise fashion as the use of the monofilament tool (Feitosa et al., 2016).

Peripheral neuropathy can also be assessed by using the pressure specified sensory device (PSSD) is a pain free test that evaluates the lower extremity for sensory deficits. The PSSD device is designed to quantify and record both specific nerve threshold levels and peripheral nerve innervation density which allows for the ability to identify pathologic changes in nerves at subclinical levels (Feitosa et al., 2016).

**LOPS.** While approximately 99% of patients who are diagnosed with DM perform their own care, most older adults with diabetes do not perform foot self-care due to problems related to aging or having functional and cognitive impairment (Sharoni, et al., 2015). The neurological clinical exam is designed to identify LOPS rather than early neuropathy. In addition to the use of the SWM, as part of the neurological exam any one of the four following clinical tests: (a) tuning fork, (b) pinprick sensation, (c) ankle reflexes, or (d) vibration perception threshold (VPT) testing should be used by the primary care provider to conduct a neurological exam to identify LOPS (ADA, 2019; Boulton et al., 2008).

Table 2.3

*Risk Assessment Scoring*

Score	LOPS or PADS	Recommendation
0	No LOPS or deformity	Annual assessment
1	Some LOPS and/or deformity	Assessment every 3-6 months
2	PADS and/or LOPS	Assessment every 2-3 months
3	History of Ulcer or Amputation	Assessment every 1-2 months

*Note.* Adapted from Boulton et al., 2015, p. 1684

**LOPS.** While approximately 99% of patients who are diagnosed with DM perform their own care, most older adults with diabetes do not perform foot self-care due to problems related to aging or having functional and cognitive impairment (Sharoni, et al., 2015). The neurological clinical exam is designed to identify LOPS rather than early neuropathy. In addition to the use of the SWM, as part of the neurological exam any one of the four following clinical tests: (a) tuning fork, (b) pinprick sensation, (c) ankle reflexes, or (d) vibration perception threshold (VPT) testing should be used by the primary care provider to conduct a neurological exam to identify LOPS (ADA, 2019; Boulton et al., 2008).

The 128-Hz tuning fork is an assessment tool that can be used to assess vibratory sensation. Vibratory sensation is an easy and inexpensive test that can be conducted by primary care providers in the outpatient setting. The test should be tested over the tip of the great toe bilaterally. An abnormal response can be defined as when the patient loses vibratory sensation and the examiner still perceives it while holding the fork on the tip of the toe (ADA, 2019; Boulton et al., 2008; Formosa et al., 2016).

The pinprick sensation test is used to assess protective sensation. A disposable pin should be applied just proximal to the toenail on the dorsal surface of the hallux, with just enough pressure to deform the skin. Inability to perceive sensation over either hallux would be regarded as an abnormal test result and is associated with an increased risk of ulceration (ADA, 2019; Boulton et al., 2008; Formosa et al., 2016).

Ankle reflex testing is used to assess the central and peripheral nervous system. Damage to a peripheral nerve produces diminished or absent reflexes (ADA, 2019).

Ankle reflexes can be tested with the patient either kneeling or resting on a couch/table. The Achilles tendon should be stretched until the ankle is in a neutral position before striking it with the tendon hammer. If the response is initially absent, the patient can be asked to hook fingers together and pull, with the ankle reflexes then retested for reinforcement. Total absence of ankle reflex wither at rest or upon

reinforcement is regarded as an abnormal study and is associated with an increased risk of ulceration. (Boulton et al., 2008, p. 1681)

Lastly, vibration perception threshold (VPT) testing is another assessment method that can be used to assess vibration perception.

This test is very similar to the 128-Hz tuning fork exam and is also tested over the pulp of the hallux. With the patient lying supine, the stylus of the instrument is placed over the dorsal hallux and the amplitude is increased until the patient can detect the vibration; the resulting number is known as the VPT. This process should be initially tested on a proximal site, and then the mean of the three readings is taken over each hallux. A VPT >25 V is regarded as abnormal and has been shown to be strongly predictive of subsequent foot ulceration. (Boulton et al., 2008, p. 1682)

***Peripheral Arterial Disease (PAD)***. The assessment of PAD is important for defining overall lower extremity risk status as it is a component in the cause of foot ulcers in approximately one third of foot ulcers and is often a significant risk factor associated with recurrent wounds (Boulton et al., 2008). A complete vascular assessment including skin assessment, temperature, and the assessment of pulses should be performed to assess for vascular insufficiency in the lower limbs (ADA, 2019; Boulton et al., 2008; Formosa et al., 2016).

Initial screening for PAD should include a history of decreased walking speed, leg fatigue, claudication, and an assessment of pedal pulses (ADA, 2019; Boulton et al. 2008). Diabetic patients who have signs and symptoms of vascular disease or absent pulses on screening foot examination should undergo ankle brachial pressure index (ABI) testing and should be considered for referral to a vascular specialist (ADA, 2019; Boulton et al., 2008). This testing is a simple and easily reproducible method of diagnosing vascular insufficiency in the lower limbs.

This test is done by measuring blood pressure at the ankle (dorsal pedis (DP) or posterior tibial arteries) using a standard Doppler ultrasonic probe (ADA, 2019). The

ABI is obtained by dividing the ankle systolic pressure by the higher of the two brachial systolic pressures. An ABI > 0.9 is normal, < 0.8 is associated with claudication, and < 0.4 is commonly associated with ischemic rest pain and tissue necrosis. (Boulton et al., 2008, p. 1682)

***Musculoskeletal foot deformity assessment.*** The musculoskeletal assessment should include evaluation for any gross deformity. Rigid deformities are defined as any contracture that cannot easily be manually reduced and are most frequently found in the digits (ADA, 2019; Formosa et al., 2016).

An important and often overlooked or misjudged condition is Charcot arthropathy. This condition occurs in the neuropathic foot and most often affects the midfoot. This condition may present as a unilateral red, hot, swollen, flat foot with profound deformity. A patient with suspected Charcot arthropathy or limited joint mobility should be immediately referred to Podiatry for assessment and treatment (Boulton et al., 2008).

### **Inspection of Footwear**

Several studies (ADA, 2019; Formosa et al. 2016; Martins de Oliveira & Moore, 2015) indicated the importance of therapeutic footwear to prevent the formation of ulcer. Inspection and provision of orders or referrals for patients to receive proper footwear is important for primary care providers to provide for patients at risk of diabetic foot complication. Examples of inappropriate shoes include those which are excessively worn or too small for the person's foot (too narrow, too short, toe box too low), resulting in rubbing, erythema, blister, or callus (Boulton et al., 2008).

Foot education should be provided to diabetic patients at every clinic visit, emphasizing the importance of avoiding the use of ill-fitting shoes and advising patients to seek the square toed shoe. Patients who have diabetic foot ulcers, limited joint mobility or those who have existing foot deformity can often times endure a reduction in healing times and can benefit from receiving information and referrals for the provision of custom measured diabetic shoes with the

use of various offloading foot devices (Martins de Oliveira & Moore, 2015). Of the available 14 different offloading devices, the total contact cast (TCC) was determined to be the most effective in the treatment of diabetic foot ulcers. Risks associated with the use of non-therapeutic shoes or failure to use prescribed diabetic shoes should be reviewed with the patient by the provider.

### **Patient Education**

Patient foot education is important for all patients living with diabetes. Improving knowledge alone is not enough to improve adherence to treatments and care regimens that involve behavioral changes. "Diabetes education is often prescriptive, offered on an as needed basis and if not continuous, so oftentimes that patient is not provided with new information on a timely basis which limits the effectiveness of existing diabetes education." (Formosa et al., 2016, p. 165)

In the literature, patient education strategies varied. For example, education was conducted in small group sessions in a health setting (Adiewere et al., 2018) and one on one discussion (Sharoni et al., 2015). Information was provided via phone follow up (Adiewere et al., 2018), self-care activities (Sharoni et al., 2015), questionnaires (Adiewere et al., 2018), demonstrations (Sharoni et al., 2015), video tapes (Adiewere et al., 2018), leaflets and handbooks (Adiewere et al., 2018) and new letters (Sharoni et al., 2015). An advantage to different modes of education delivery is that it allows the person who is diagnosed with diabetes and the provider to implement education in the most effective way to promote foot self-care adherence and compliance. A disadvantage to the availability of a variety of patient care delivery modes is that in many clinical settings, all modes are not feasible for use, may be considered too expensive to offer or implement, or may be too complex for persons with cognitive impairment, lower level of literacy or advanced age to use effectively.

Several studies supported a multidisciplinary approach for the provision and delivery of patient foot self-care education (Ada, 2019; Adiewere et al., 2018; Formosa et al., 2016; Sharoni

et al., 2015). Education should be delivered to the patients by personnel trained about diabetes management and can include the PCP, diabetes educator, or specialty podiatry provider. The advantage to patient education by these specially trained individuals is that the quality of the information being provided is likely higher than that of the average lay person in the community (Sharoni et al., 2015).

Diabetic patients and their families should receive foot self-care education that includes information about risk factors for diabetic foot complication, appropriate management of diabetic foot care, an understanding of the implications of foot deformity, information about LOPS and PAD, nail and skin care, and the importance of foot monitoring on a daily basis.

Patients who have LOPS should be educated about the importance of daily visual foot assessment for surveillance of early foot problems. The importance of appropriate footwear and footwear behaviors should be reviewed with patients as well. Patients should be cautioned and advised to ambulate with shoe protection at all times. Patients who have visual difficulties, physical constraints which prevent movement, or cognitive problems that impair their ability to assess the condition and to institute proper responses will require assistance from family, friends or the referral to home care services to assist with their care. (ADA, 2019, p. S134)

Foot self-care education should be provided to every diabetic patient at every primary or specialty diabetic patient care clinic encounter. The frequency of follow up foot reassessment is determined by the foot risk score assessment outcome (ADA, 2019).

### **Multidisciplinary Approach**

Review of current literature supports a multidisciplinary approach to the screening, assessment and management of diabetic foot care in the primary care setting (ADA, 2019; Formosa et al., 2017; van Acker et al., 2014). Cross training providers to provide frequent, thorough, diabetic foot risk assessments and incorporating diabetic foot care into a combination of both primary and specialty care service encounters will assist in the frequent monitoring, early

identification, treatment, and referral of diabetic patients to enhanced diagnostic testing and specialty care services that is needed to ensure the highest level and quality of care is delivered aimed at improving patient outcomes.

### **Best Practice Model Recommendation**

Review of the appraised evidence used for this EBP project indicate that the *American Diabetes Association Standards for Medical Care in Diabetes 2019-Abridged for Primary Care Providers* (ADA, 2019) is the best practice model recommendation for the screening of risk, prevention, and treatment of diabetic foot complication and improving patient outcomes for diabetic patients seen in the primary care setting. This nine-step multifactorial approach is presented in Table 2.4.

### **The Most Appropriate Intervention to Answer the Clinical Question**

Based on the evidence, the PICOT question for this EBP project is “In adult diabetic patients ages 18-74 seen in the primary care setting, does a multi-faceted intervention, compared to previous clinic foot care practices. result in referrals that are more appropriate, improved provider assessment, and increased patient compliance with follow-up appointments over a 12-week period? The evidence-based multi-faceted intervention included: (a) implementing provider history and foot physical assessment including provider use of the Semmes Weinstein Monofilament (SWM) tool to assess for actual diabetic foot complication, (b) assessing of footwear, (c) providing patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback. This EBP project involved the implementation of the nine recommendations developed by the American Diabetes Association (ADA, 2019) into the clinical setting being used.

Use of the EBP Model: The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) assisted with actively engaging the staff in the implementation process. Sustaining the project required modifying the implementation process so that it is feasible to employ the multifaceted intervention in the

Table 2.4

*Nine Step Approach to Foot Assessment for Diabetic Patients*

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1. Perform a comprehensive foot evaluation at least annually to identify at least risk factors for ulcers and amputation (B)
  2. Patients with evidence of sensory loss or prior ulceration amputation should have their foot inspected at every visit (C)
  3. Obtain a prior history of ulceration, amputation, Charcot foot, angioplasty or vascular surgery, cigarette smoking, retinopathy, and renal disease and assess current symptoms of neuropathy (pain, during, numbness) and vascular disease (leg fatigue, claudication) (B)
  4. The examination should include inspection of the skin, assessment of foot deformities, neurological assessment (10g monofilament assessment: pinprick, temperature, vibration) and vascular assessment including pulses in the legs and feet (B)
  5. Patients with symptoms of claudication or decreased or absent pedal pulses should be referred for ankle brachial index and for further vascular assessment as appropriate (C)
  6. A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet (e.g. dialysis patients and those with Charcot foot or prior ulcers or amputation.) (B)
  7. Refer patients who smoke or who have prior history of lower extremity complications, loss of protective sensation, structural abnormalities or peripheral arterial disease to foot care specialists for ongoing preventive care and lifelong surveillance (C)
  8. Provide general preventive foot self-care education to all patients with diabetes (B)
  9. The use of therapeutic specialized footwear is recommended for high risk patients with diabetes including those with severe neuropathy, foot deformities or history of amputation (B)
- 

*Note.* Recommendations for the provision of diabetic foot care in clinical practice

clinical setting of this EBP project. This flexibility of implementation assisted both the leadership and clinical staff to remain optimistic about the changes being implemented that were aimed at promoting best patient outcomes. Internal and external dissemination of the project results enhanced the knowledge base of all involved stakeholders using evidence-based research to promote high level, high quality evidenced-based patient outcomes.

## CHAPTER 3

### IMPLEMENTATION OF PRACTICE CHANGE

Doctorally prepared nurses frequently use theories and models to guide changes in the practice setting. To implement this EBP project, The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) was used. Step one of this model was to identify the triggering issues and opportunities. The identified trigger for this EBP project was the need for diabetic patients seen in the primary care setting to receive diabetic foot risk assessment to assist in determining the risk for the development of diabetic foot complication. Organizational leadership determined that the PCP's of this facility were in a strategic position to promote early intervention and referral to specialty podiatry services by performing and documenting diabetic foot assessments for diabetic patients who are cared for in the primary care setting. It is expected that by improving foot assessment and treatment by PCPs, overall risk for diabetic foot complication would be reduced. Based on this identified need, the following PICOT question was posed: "In adult diabetic patients ages 18-74 seen in the primary care setting, does a multi-faceted intervention, compared to previous clinic foot care practices, result in referrals that are more appropriate, improved provider assessment, and increased patient compliance with follow-up appointments over a 12-week period?" The evidence-based multi-faceted intervention included: (a) implementing provider history and foot physical assessment including the use of the Semmes Weinstein Monofilament (SWM) tool to assess for actual diabetic foot complication, (b) assessing of footwear, (c) providing patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback. The aim of this project was to determine if a multi-faceted approach to the provision of provider foot care has improved diabetic foot care in the EBP project clinical setting.

Prior to implementing foot assessment of diabetic patients in the primary care clinic, the PL focused on steps one through seven of the Iowa Model Revised: Evidence-Based to Promote Excellence in Health Care (Iowa Model Collaborative, 2017). These steps include identifying the triggering issues and opportunities, stating the question or purpose, prioritizing the topic, forming a team, appraisal and synthesis of the evidence and designing and piloting the change in practice to guide the order for the implementation of this EBP project. To accomplish being successful with project implementation, the PL integrated scholarship, clinical expertise, and best practice to impact and change practice behaviors that support safe, efficient, effective patient care to improve patient outcomes. This chapter provides a detailed account of the process undertaken by the PL to transform and integrate evidence of best practice recommendations into clinical practice at the EBP clinical site to promote practice change and improve patient outcomes.

### **Setting and Participants**

#### **Setting**

The project setting for this EBP project was a low income, public primary care clinic located in a large urban community in the Midwestern region of the United States. This outpatient adult medicine clinic was a part of a large public teaching hospital that primarily provides medical care services to the uninsured, underinsured residents of the jurisdictional county and surrounding counties in the area. This clinical setting was selected because of an observed need for improved diabetic foot care intervention and the PL's vested interest in making an impactful difference in the adult diabetic patient population serviced at the PL's place of employment.

This outpatient primary care clinic exists within a large clinic with 70 exam rooms. Staff provide care services to approximately 350 patients per day or 59,000 adult patients annually. In addition to primary care, this clinical facility has specialty care services on-site that are accessible to patients via provider referral. Both the outpatient primary care and specialty

Podiatry services are conveniently located on the same campus near a major inner-city interstate expressway and public transit system.

### **Participants**

This EBP project participant population was composed of a diverse ethnic mix due to the large geographic area served by this clinical site with a vast majority of the patients being of African American, Hispanic, and Polish descent. As needed, this facility utilized a state-of-the-art professional medical web based language interpretation system, which had the ability to assist staff with communicating with patients in over 200 languages within minutes of initiating the request. As noted in the literature, patients who have diabetes provide 99% of their own care; however, that most people who are diagnosed with diabetes do not perform foot self-care due to problems related to aging or having functional or cognitive impairment (Sharoni, et al., 2016). It is likely that patients in this clinical setting are similar.

In addition to these patient participants, HCPs were also EBP project participants because they were the ones conducting the foot assessments. Provider participants included the clinical and ancillary support staff on Team A in the primary care clinic. Other participants include specialty PC physicians, senior leadership, risk management, and information technology (IT). Cumulatively, the clinical care team at this EBP project site encompasses a wide range of comprehensive clinical and professional expertise.

**Patient participants.** For this EBP project, patients were included who are either male and or non-pregnant females and are ages 18-74. Patients who were diagnosed with type I and type II diabetics were included because both types of diabetes can cause micro and macrovascular damage to blood vessels and peripheral nerves that can result in problems with the legs and feet (Boulton, et al., 2008, Feng, et al., 2011, Sharoni, et al., 2016 and Wang, et al., 2017). Individuals were included regardless of their compliance to prescribed regimen, level of cognitive functioning, or literacy level. Patients who have previously had a diagnosed diabetic foot complication were included because they are at greater risk and therefore, require

assessment that is more frequent. Individuals who are non-diabetic, under 18 years of age or over 74, or have bilateral lower extremity amputation were ineligible for participating in the project. Patients who were co-managed within the last 12 months by in house or external Podiatry specialty services were excluded. Excluded patients were not provided with information regarding the importance of foot screening, frequency of screening, rationale for screening, and/or anticipated outcomes of being screened.

Many of the patients who receive medical care at this facility are insured under state and or federal insurance benefit programs that were made available as a direct result of the ACA. Signed into law in March 2010, the ACA was designed to slow the rise of healthcare costs by providing high quality, comprehensive health care coverage for those in need of health care services at an affordable cost.

**Provider participants.** Team A in the general medicine outpatient clinic consists of physicians and nurse practitioners. They are responsible for assessing and treating the patients who are diagnosed with diabetes. Clinicians are board certified licensed physician or nurse practitioner providers in the primary care setting. They provide medical care services to adult diabetic patients receiving care in the general medicine clinic.

The clinical care team, known as Team A, consists of 8 physicians, who are licensed personnel responsible for addressing the patients' health concerns, including health maintenance. They have accountability for referring patients to specialty services as applicable. There are 5 females and 3 male physicians who possess approximately 12-15 years of clinical practice experience.

The team also has two female nurse practitioner (NP) clinicians, defined as licensed personnel (often referred to as a midlevel provider) who are also responsible for addressing the patients' health concerns, including health maintenance. Like physicians, they also have accountability to referring the patients for specialty services. One NP has 6 years of clinical experience while the other has 7. One of the NPs is the PL. Aside from common medical

knowledge, these providers have not received formal department provided in-service training on proper use of the SWM tool and have not been routinely performing or documenting formal foot risk assessments on the adult diabetic patients seen in the primary clinic setting.

The rationale for limiting this EBP project to Team A was because incorporating the large volume of diabetic patients seen across the 3 teams which comprise the entire clinic would not be feasible and would be unrealistic to attempt with the limited staff support and allotted time by which the PL has available to complete this EBP project. In addition, the PL and site preceptor are both members of Team A which will allow the PL to be directly involved in the implementation process.

Pre-intervention characteristics of the specialty PC providers include that they are board certified physicians who provide specialty care services in the PC setting to all patients (to include diabetic) in need of specialized foot care services. The Podiatry physician providers are trained as part of their professional clinical and academic preparation in the proper use of the SWM tool, rationale for use, benefits of early assessment and intervention and anticipated patient outcomes.

**Ancillary staff participants.** The ancillary clinic staff on Team A in the primary care clinic include two licensed registered nurses, four medical assistants, and one team clerk. There are 2 team registered nurses who are licensed clinical staff capable of assessing, teaching, and performing duties within the nursing licensure limitations for the respective state of clinical practice. Each of these female nurses has approximately 10 years of clinical experience, each with 5 years inpatient hospital and 5 years of clinic experience. The four certified medical assistants support the work of physicians and NPs in the clinical setting consisting of 1 male and 3 females. On average, the medical assistants possess approximately 5 years of clinical experience each. Lastly, Team A has 1 female team clerk who has approximately 10 years of clinical administrative clerical experience. On inquiry, these ancillary team members have not

received formal use training or having a working knowledge of the indication or rationale for SWM tool use.

When foot complications were identified, primary care providers referred patients to the specialty podiatry clinic. The specialty PC providers are board certified physicians who provide specialty care services in the podiatry clinic setting to all patients (to include diabetic) in need of podiatry services. These providers are specifically trained about the proper use of the SWM tool, rationale for use, benefits of early foot assessment and intervention and anticipated patient outcomes.

**Leadership participants.** The organizational leadership involved in this EBP project includes a committee of non-clinical management. These individuals have collectively reviewed the literature for best practice pathways to improve patient care and outcomes. While not possessing direct hands on clinical experience in the use of the SWM tool on diabetic patients to assess risk for diabetic foot complication this group has reviewed high level, high quality evidence in the literature which supports the implementation of best practice that will promote safe, effective, cost efficient care while improving patient outcomes.

### **Intervention**

The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) guided the practice change. A comprehensive review of the literature was performed to identify best practice for the implementation of provider assessment of diabetic patient risk for diabetic foot complication in the primary care setting. The PL synthesized the literature to develop an evidence-based systematic approach to diabetic foot assessment by primary care providers at the clinical site used for this EBP project.

Based on a systematic review of the literature, it was determined that for patients who are diagnosed with diabetes best practice is fourfold: (a) a thorough history and physical examination of the feet, including provider use of the SWM tool, (b) assessment of foot wear, (c) the provision of patient self-care foot education, and (d) the use of a multidisciplinary approach.

To achieve best practice, education was provided to both provider and ancillary staff participants, a workflow will be planned and implemented, and ongoing feedback was provided.

### **Provider Education**

Education included content about the proper use of the SWM tool, how to conduct a thorough foot history and foot physical assessment, and how to inspect patient footwear. The provider educational tutorial also included talking points to be included by providers when providing patient education about basic self-care foot and skin care for patients, guidance regarding when to make a referral to the specialty podiatry clinic, and the process for evaluating and determining the frequency of when providers should conduct foot assessments. Lastly, provider education content included basic education about signs and symptoms of foot complication that providers should review with patients to ensure foot care safety.

At the EBP project clinical site, PCPs did not currently conduct a thorough history and physical examination of the feet of patients who have diabetes, therefore, staff education was provided. While one-on-one education has been identified as the most effective way to change clinical practice (Sharoni, et al., 2016), organizational leadership indicated that this would not be realistic due to the massive size and structure of the clinical site, as well as limited time, limited staff resources, and financial constraints. It has been determined that it was more feasible and realistic to provide staff education via the use of a foot care video tutorial and a foot care tip sheet. The initial plan to implement provider foot education using a web-based Learning Module Software (LMS) tutorial had to be modified due to the inability to coordinate module development assistance between the PL and the information technology (IT) department within the time constraints of this EBP project timeline.

In place of this web-based educational platform, the Podiatry Department physician chairperson co-developed a video tutorial link demonstrating the proper steps for providers to follow when performing a foot assessment. In accordance with the NCQA (NCQA, 2019) and ADA standards for diabetic foot care (ADA, 2019), the provider foot education video was

established in collaboration with a blue-ribbon panel team consisting of the divisions of Podiatry, Neurology, Endocrinology and General Medicine providers at the Project X EBP clinical site.

The video is accessible at: (<http://cchhs1->

[my.sharepoint.com/y/g/personal/dvittumcookcountyhhs\\_org/EdPj\\_i2fWltPu9bEd\\_uQm\\_4BuVPq\\_bB2cgt6O5s7LCrOlyA?](http://my.sharepoint.com/y/g/personal/dvittumcookcountyhhs_org/EdPj_i2fWltPu9bEd_uQm_4BuVPq_bB2cgt6O5s7LCrOlyA?))

In addition, HCPS were provided with a tip sheet (Appendix B) developed by the Division of Podiatry at the EBP project clinical site. Additionally, this same multidisciplinary group developed a foot care tip sheet that includes information about the key components of the foot assessment: **(T)**emperature, turgor, **(I)**nspect, integrity, **(P)**ulses, palpate, and **(S)**ensation.

Over the duration of EBP project period, the PL provided daily face-to-face reminders for providers to view the SWM tool demonstration video. In addition, the PL created a handy pocket-sized laminated identification card (ID) clip on version of the foot care tip sheet and a foot exam step by step pictorial as a quick reference for providers to use as needed. The foot exam tutorial video link was later added to the ID card to assist in quickly directing staff to the foot care video link when needed (Appendix B). The PL used the daily pre-shift morning huddles to provide weekly provider project data feedback, clarify any staff concerns related to the project and to review the project workflow algorithm to ensure all staff participants were clear on their role in this change process. According to the Center for Excellence in Primary Care (CEPC) huddles have been shown to be an effective method of interdisciplinary education (CEPC, 2013).

### **Workflow**

Workflows can help streamline and automate repeatable tasks, minimizing room for errors and increase overall efficiency (Hague, et al., 2008). A process for implementing the diabetic foot assessment has been proposed. The workflow begins when a patient arrives at the clinic and is registered by the team clerical person. The medical assistant assigned to the respective providers on the team triages the patient and obtains vital signs as well as

determines the patient's diabetes diagnosis status by reviewing the problem/diagnosis screen in the EMR. To flag a particular patient for health care providers, the medical assistant places a patient label for each identified diabetic patient in the designated team log book. This log book was created by the PL to track diabetic patients seen on Team A daily. The medical assistant escorts the patient to an examination room and advises the patient to remove his/her shoes for the provider to perform the diabetic foot risk assessment. As part of the exam room set up, the medical assistant places a SWM tool on the countertop in the exam room for the provider to use to complete the diabetic patient foot assessment to aid in determining patient risk for diabetic foot complication. See Appendix C to review the EPB project site diabetic foot workflow algorithm chart. Additionally, as part of implementing the workflow process, the PL met with Team A clinical staff to determine the best location to store the EBP project log book, SWM tool supplies, and to determine the best place to post the laminated workflow algorithm for all Team A project participants to see and reference.

### **History and Physical Examination**

Histories and physical examination were conducted by the Team A physicians and NPs. For a history, providers asked patient participants. The provider generally started off with broad open-ended questions regarding the patients diabetic foot history to begin the interview, followed by more focused open-ended questions to obtain more specific information such as a history of previous ulcer or amputation is obtained and finally the provider used more closed-ended questions to assess key issues regarding the patient's foot care history that may be important to the differential diagnosis, but not mentioned earlier in the interview by the patient or to further clarify information regarding the patient's foot history that was previously obtained. Lastly, the provider reviewed and provided the patient with basic self-care foot education.

The provider exposed both lower extremities to ensure the completion of a thorough foot risk assessment. Examining one extremity at a time, the provider first inspected each lower extremity for changes in skin integrity which included assessment of signs of erythema, ulcer,

and changes in hair distribution. This inspection included the anterior, lateral and posterior skin surfaces. Each foot was included in the assessment of skin of the soles, heels and in between each toe.

Next the provider assessed the skin temperature and presence of pulses of each extremity and foot. Pulse assessment and palpation included the popliteal, which is located behind the knee, posterior tibial (PT) pulse, which is located at the ankle and, the dorsal pedal (DP) pulse, which is located at the anterior surface of the foot. Capillary refill of the toenail bed was also assessed.

Monofilaments in the EBP project clinical setting are for single patient use only. Per best practice recommendations, testing should be done at least once per year or when a new foot ulcer occurs as part of an overall foot assessment (ADA, 2019). To complete the exam using the 10g monofilament (Appendix D), the provider completed the assessment of sensation in each foot. Placing the monofilament perpendicular with the skin, the provider assessed the first, third and fifth toes, the first, third and fifth metatarsal, outside and inside of the arch, at the heel and, on top of the foot at the first inner space to test the deep peroneal nerve (Appendix E). The provider applied pressure until the monofilament buckled. In addition, the provider assessed the strength of each lower extremity and foot. Using the designated provider documented template, the provider documented the exam in the EMR. The SWM assessment risk score determined the need for specialty or continued PCP follow-up and determined the frequency of foot assessment by the clinical provider.

Best practice recommendations identify the SWM tool as the “gold standard” assessment tool to be used by providers for diabetic foot assessment (Feitosa, et al., 2016). The low cost, ease of use, reliability and validity are reasons noted for its high reviews in the literature (Feitosa et al., 2016). Risk category scores range from 0-3. A score of 0 denotes diabetes, but no loss of protective sensation in feet. The score of 1 denotes diabetes, loss of protective sensation in feet. The score of 2 denotes diabetes, loss of protective sensation in feet

with high pressure (callout/deformity) or poor circulation. The score of 3 denotes, diabetes, history of plantar surface ulceration or nephrotic fracture.

Management of risk is very important. Foot ulcers and amputations are a major cause of morbidity, disability, as well as emotional and physical costs for people with diabetes. Early recognition and management of independent risk factors can prevent the risk of adverse outcomes (Sims et al., 1988). Patients with a risk score of 0 should receive education emphasizing disease control, proper shoe fit/design, annual foot screen follow-up and follow up as needed for skin, callous, and nail care or orthoses. Patient risk score of 1 should receive education emphasizing disease control, proper shoe fit/design, daily self-inspection, skin/nail care, early reporting of foot injuries, proper fitting/design footwear with soft inserts/soles, routine follow-up in 3-6 months for foot/shoe exam and nail care. Risk score of 2 education emphasizing disease control, proper shoe fit/design, daily self-inspection, skin/nail care, early reporting of foot injuries, depth-inlay footwear with soft in-soles, routine follow up in 1-3 months for foot/activity/footwear evaluation and callus /nail care. A risk score of 3 should receive education emphasizing disease control, proper shoe fit/design, daily self-inspection, skin/nail care, early reporting of foot injuries, proper fitting/design footwear, early reporting of foot injuries, depth-inlay footwear, molded/modified orthoses; modified/custom footwear, ankle foot orthoses as needed, routine follow-up 1-12 weeks for foot/activity/footwear evaluation and callus /nail care.

### **Assessment of Footwear**

Preventing foot ulcers in individuals who are diagnosed with DM is a major clinical objective for providers because foot ulcers can lead to lower limb amputations (Maciejewski, et al., 2004). HCPs should carefully evaluate footwear apart from foot care and foot education to ensure diabetic patient shoe selections are not contributing to the risk of diabetic foot complications. Diabetic shoes are specially designed to offer protection for diabetic feet and to reduce the risk of skin breakdown, primarily in cases of poor circulation, neuropathy, and foot

deformities. Some of the standard features of diabetic shoes include: (a) Achilles tendon protector, (b) high collar which cushions the ankle, (c) supportive upper which holds the shoe on the foot, (d) Insole which cushions and supports the foot and arch, (e) gel, foam or air midsole reduces impact when the foot strikes the ground, (f) outsole assists with the maintaining shoe traction, and (g) toe box provides space for the toes which will assist with preventing calluses (Sparks, 2017). Therefore, it is essential for PCPs to assess the footwear worn by diabetic patients at each clinic encounter and to recommend and/or prescribe appropriate footwear suitable to achieve optimal diabetic foot care outcomes diabetic patients.

### **Patient Education**

In accordance with current clinical practice guidelines (ADA, 2019), this PL created a Patient Self-Care Foot Education Pamphlet (Appendix F) incorporating information about general preventative diabetic patient foot self-care education. Handouts are included with the discharge summary document and are provided to all patients who are diagnosed with diabetes. Content for the handout is based on best practice recommendations for patient educational foot self-care content and will follow the ADA guidelines (ADA, 2019).

Due to the large volume of low literacy patients serviced at the EBP project site, modifications to the language of the ADA guidelines (ADA, 2019) for foot care education were made. Ideas for modifications that may prove effective in the EBP setting include the use pictures (ADA, 2019) and short phrased sentences (ADA, 2019) explaining self-care management steps more likely to promote patient engagement in self-care.

When developing the self-care foot education pamphlet for the patients receiving care at the EBP project site, the PL utilized evidence from the literature to support the main message of the importance of diabetic patients receiving regular clinical foot exams as well as for recommendations to reduce the risk for the development of diabetic foot complication. In response to the low literacy rate and prevalence of language barriers in the patient population at

the EBP project site, pamphlet design layout included short phrased sentences and colorful photo examples of important concepts (Appendix F).

In accordance with updated requirements of meaningful use (Shipman, Lake, Van Der Volgen & Doman, 2016), patient education at the EBP project clinical site was disseminated electronically via the discharge summary. The PL expressed interest to both leadership and to the information technology (IT) department in contributing to the layout and design of the diabetic patient home care foot education content portion of the patient discharge summary.

### **Multidisciplinary Care**

A multidisciplinary approach is recommended for individuals who have foot ulcers or have high-risk feet (e.g., dialysis patients and those with Charcot foot or prior ulcers or amputations) (ADA, 2019). Incorporating diabetic foot assessment into primary care allows for early assessment, diagnosis, intervention, and referral to specialty services. The categorized score obtained by providers from the assessment of diabetic foot complication risk using the SWM tool determines the frequency in patient follow up and the urgency of additional diagnostic testing and treatment.

At the EBP project clinical site, there was an electronic referral system to refer patients to specialty clinics. Providers determined the necessary referral a patient may need and placed the order in the EMR. Generally, patients were randomly assigned an appointment date with the requested specialist within 15-20 days of the order. Patients were typically scheduled to be seen by the specialist within 30-60 days of the initial referral submission.

Before the implementation of this project, PCPs were omitting the foot exam and referring to the specialty podiatry clinic without conducting a baseline foot assessment. Less than 20% of diabetic patients seen in the EBP project primary care setting in the last 12 months had a documented foot exam in the EMR (CMAPP, 2018). Senior leadership determined this practice to be a flagrant misuse of referral resources. This resulted in an unusually prolonged timeframe for patients to be seen in the PC and low to no provider documentation of diabetic

patient foot assessments in the EMR. A task force of clinicians, administrators, and IT personnel convened to brainstorm ways to work more safely, effectively, and efficiently to improve identified workflow concerns while improving diabetic patient outcomes.

As the project was implemented, the new criteria for making referrals was used by Team A providers. As previously mentioned, patients were referred to the PC when the SWM tool score is determined to be a 3.

### **Feedback to Providers**

Compliance with clinical practice guidelines improves when health care providers receive ongoing feedback during the change process (ADA, 2019; Boulton, et al., 2008; Formosa et al., 2016). Statistical data about the EBP outcomes was provided to participating clinical staff. Using message center via an organizational password protected intranet portal, the PL has shared the tutorial training link reminders. The daily pre-shift huddles were used to provide feedback aggregated data with provider participants. Both these strategies helped keep each project participant in the loop regarding project status and progress.

To monitor the progress of the practice change, weekly EMR audits of randomly selected patients were used to measure three outcomes which included: (a) patient access to specialty podiatry services, (b) provider compliance with foot risk assessment, and (c) provider compliance with foot risk assessment documentation. Pre-, intra- and post-data were recorded on a variable intake form (Appendix G) and later transferred to an Excel spreadsheet. Percentages were calculated for the purpose of reporting to staff their overall progress. Reporting the results as percentages allowed for a clearer understanding of the difference (if any) in the pre-, intra- and post-intervention group comparisons. Data were de-identified and aggregated when disseminated among project participants and leadership, as well as formally presented in oral and poster presentations at the university.

### **Comparison**

In addition to numerous instances of PCP failure to provide foot assessment service for adult diabetic patients seen in the primary care setting, statistical data from the EBP project clinical site was used to fuel the PL's EBP proposed practice change. In 2018, this clinical site identified 18,221 patients as being diabetic. Of this total, excluding those being co-managed by a specialty clinic (podiatry or diabetes clinic) less than 20% of these identified patients seen in the outpatient general medicine clinic setting had a documented clinical foot exam in the EMR (CMAPP, 2018).

The PL compared previous Team A care provider practices to data collected during the EBP project. Data were collected about the same outcomes that were reported as feedback to the providers. The PL performed EMR audits of randomly selected diabetic patients who met the inclusion criteria for the project and who attended the outpatient primary medical care clinic project site the 8-weeks prior to implementation of the EBP project. These data were compared to the data collected during the 12-week project period to determine if there was a statistically significant improvement in the diabetic care being provided to patients. Pre-intervention data were de-identified and aggregated for dissemination among project participants, leadership, and the presentations.

### **Outcomes**

The EBP project focused on one primary and two secondary outcomes. The targeted primary outcome was to increase the number of appropriately referred patients to the PC based on the SWM score. The PL selected to focus on this outcome after learning of organizational leaderships report which supported flagrant provider misuse of the EMR referral system process as evidenced by determination that referrals were being made without baseline clinic foot risk assessments being conducted by providers.

The first secondary outcome was to increase the number of diabetic patients being assessed for actual diabetic foot complication. The PL selected this outcome as a result of

reviewing organizational documentation which confirmed less than 20% compliance of diabetic foot risk assessment documentation by primary care providers (CMAPP, 2018).

The second, secondary outcome was to increase patient follow-up compliance with referral to the PC scheduled. The PL determined this outcome to be significant due to the large volume of diabetic patients reported at the EBP project site that did not currently or previously have foot care service documented in the EMR, likely due to low or no-show compliance with attendance to foot care appointments in the remote past.

Data were collected on the variable intake form (Appendix G) and was then transferred to a Microsoft Excel spreadsheet. Patient medical record numbers were recorded so that charts could be audited twice. For data collected during the EBP project implementation, the first audits were to collect demographic data and information regarding provider foot assessment and referral. These audits were conducted weekly over the course of 12 weeks so that data could be shared with HCPs by the PL to provide feedback about project progress. The second audit was conducted later to ascertain whether patients attended the referral to the PC. Data about patients in the outcomes group were collected at one time from the EMRs. Data were attainable via a manual chart audit performed by the PL.

The 10g-SWM tool was used to measure the risk for diabetic foot complication assessment for diabetic patients seen in the primary care setting as it remains the gold standard with a reported sensitivity and specificity of 0.95 to 0.82 for the diagnosis of loss of sensation, proving its efficiency and reliability (Feitosa et al., 2016) for this EBP project.

### **Time**

Planning sufficient time for changing practice was paramount to achieving optimal outcomes (Tilter, 2008). The PL created a GNATT Chart (see Appendix H) for Actual Timeline because this strategy allowed the PL to plot project goals on a shared calendar that assisted in ensuring the PL remained both organized and accountable in completing the listed tasks. To collect data about the comparison group, the PL retrospectively reviewed EMRs for diabetic

patients from an 8-week time span. The tentative time frame set for this was August 2019 to October 2019. Tasks to complete this process included the PL leader reviewing past provider schedules, identifying diabetic patients, randomly auditing charts of those identified to determine assessment, documentation of feet assessment and referral (if indicated) and patient attendance to specialty Podiatry services.

The intervention was implemented over a 12-week period and occurred from October 2019 to December 2019. During this time, provider education was provided, and clinician workflow modifications were implemented. Tasks to complete this process included randomly selecting EMRs from diabetic patients seen at the clinical. These were selected from the team diabetic log book, which was created at the start of the implementation process to determine provider assessment, documentation, and referral and patient access to specialty Podiatry services (if indicated). Weekly participant feedback was provided by the PL to clinical project participants during weeks 6 through 12 of project implementation.

Data analysis occurred in March 2020. The major focus of the analysis was to successfully answer the PICOT question. Tasks which were completed during this time frame included the PL manually reviewing randomly selected EMRs to determine provider diabetic foot assessment rates, referral based on tool score result and patient compliance to the specialty foot clinic follow-up

For the success of this EBP project, the projected Fall 2019 timeframe fell in alignment with the government fiscal year budget approval. The SWM tools were not previously available in the outpatient medical clinic. The purchase of the tools was dependent on the budget cycle. Typically, public hearings are held annually in July, followed by balancing of departmental requests by the county president in September. In October, the board president submits the executive budget recommendations to the finance committee, and during October and November the budget is made available to the public. The process ends in December 2019 as the fiscal year begins. The PL worked closely with leadership and was able to obtain SWM tool

stock order approval in the Fall of 2019. Actual SWM tool product shipment was received by the EBP project site and PL in late Oct 2019; just in time for implementation.

### **Protection of Human Subjects**

It is always imperative to maintain the protection of human subjects when translating and implementing evidence-based knowledge into practice in the clinical setting (Peled-Raz, 2017). On April 21, 2019, the PL completed the Citi Program university mandated Institutional Review Board (IRB) training course and received a certificate (Appendix I) for the completion of the web-based training course entitled, "Social Behavioral Educational Researchers." This certification is a requirement of the University where the PL is studying. Additionally, the preliminary questionnaire to determine the type of IRB application needed for this EBP project was completed on July 19, 2019. Results from the questionnaire showed that this EBP project did not require IRB review; therefore, no formal IRB application was required.

The PL successfully completed and submitted the self-guided tutorial designed to familiarize individuals with federal regulations and the EBP project sites policy concerning the use of human participants in research as mandated by the PL's place of employment. The project clinical site also mandated an in person 2-hour class training session (Appendix J) which was successfully completed on July 23, 2019. Upon further communication with the PL's faculty advisor and site facilitator, the PL submitted an exempt application to the clinical facility IRB for review. Per organizational risk management, no additional IRB application submission is indicated for this EBP project.

To protect patient confidentiality, raw data shared with advisors had the medical record numbers removed from the Microsoft Excel spreadsheet. Hardcopy data was stored in a locked file drawer in the PL's office at the EBP clinical site. When it was time to discard hardcopy data, all identifiers were removed, and materials were discarded in the clinical site provided locked recycle bins for proper disposal. Electronic data was stored in the PL's password protected

personal computer. Patient confidentiality was maintained in accordance with the Human Insurance Portability and Accountability Act (HIPPA) law.

Protecting the rights of HCPs who were involved in this EBP project was also a consideration. For example, it would be unethical to identify an HCP who has poor compliance with the practice change. Therefore, only aggregated data were shared with HCPs and reported publicly in reports and presentations.

## **CHAPTER 4**

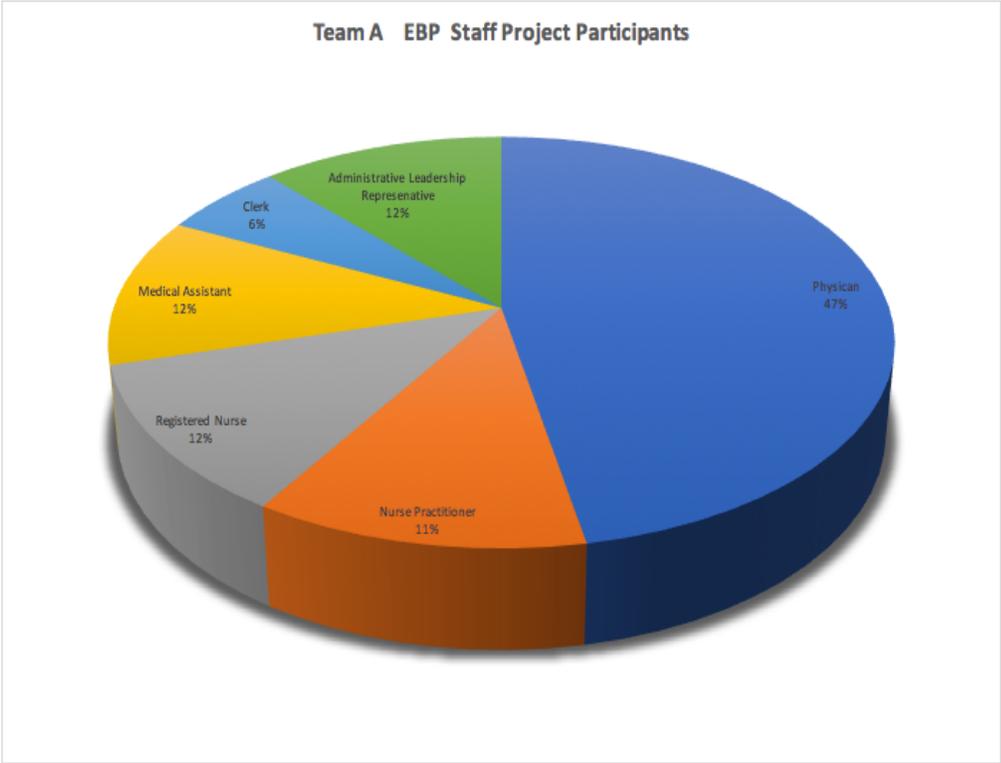
### **FINDINGS**

The purpose of this EBP project was to implement a multi-faceted intervention to assess diabetic patients for actual foot risk complication in the primary care setting. The project consisted of strategies identified from the literature as best practice recommendations to be effective in reducing diabetic patient risk for foot complication. Outcomes for the project included appropriate referrals, provider foot risk assessment and patient follow up compliance to the podiatry clinic. The PICOT question for this project was: In adult diabetic patients ages 18-74 seen in the primary care setting, does a multi-faceted intervention, compared to previous clinic foot care practices, result in referrals that are more appropriate, improved provider assessment, and increased patient compliance with follow-up appointments over a 12-week period? This evidenced based multi-faceted intervention included four strategies: (a) implementing provider history and foot physical assessment including the use of the Semmes-Weinstein Monofilament (SWM) tool to assess for actual diabetic foot complication, (b) assessing footwear, (c) providing patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow and providing ongoing feedback.

#### **Participants**

Project participants included the clinic staff who worked on Team A at the EBP project clinical site when data were collected for this EBP project. Staff disciplines were 8 physicians, 2 nurse practitioners, 2 registered nurses, 4 medical assistants, 1 team clerk and the PL who led the practice change. Randomly selected diabetic patients who received patient care on Team A, who met the inclusion criteria during the project pre-intervention, implementation and post intervention time frame were included in the data set (see Figure 4.1).

Figure 4.1 Team A EBP Staff Project Participants



### **Size and Characteristics**

**Pre-Intervention group characteristics.** An 8-week, retrospective chart audit was conducted by the PL using a selection of charts that were randomly selected for patients seen by one of the 8 physicians and 2 nurse practitioners of Team A. To be included in the audit, charts were from diabetic patients, ages 18-74, who had a documented diabetic clinic visit between August 9, 2019 and September 27, 2019. Because 25 charts were selected over the 8 weeks, the pre-intervention patient participant population was 200. To describe the sample, data were collected regarding patient participant characteristics including age, gender, race, marital status, number of years diabetic, serum HbA1C result, history of single limb amputation, provider type, and insurance type (Table 4.1). Data were also collected regarding foot exam by provider, monofilament tool score, referral to podiatry, and referral appointment compliance as these data were necessary for the PL to analyze the primary and two secondary outcomes.

**Intervention group characteristics.** A 12-week intervention chart audit was conducted by the PL using 25 randomly selected charts per week for patients seen by the 8 physicians and 2 NPs of Team A. To be included in the audit, charts were from diabetic patients, ages 18-74, who had a documented diabetic between November 4, 2019 and January 24, 2020. This audit yielded an intervention patient sample of 306 participants.

**Post Intervention group characteristics.** A 1-week post intervention chart audit was conducted by the PL using a selection of charts that were random for patients seen by the 8 physicians and 2 NPs of Team A 3 weeks post project implementation. To be included in the audit, charts were from diabetic patients, ages 18-74, with a documented diabetic clinic visit between February 17, 2020 and February 22, 2020. This audit yielded a post-intervention patient sample of 25 participants. Data collected about patient characteristics were collected.

TABLE 4.1

*Demographic Data*

Variable	Pre-Intervention (n=200)	Intervention (n=306)	Post-Intervention (n=25)	Total (n=531)
Age Mean (SD)				53.77 (12.19)
Gender % (n)				
Female	58% (n=112)	57.5% (n=178)	44% (n=11)	56.7% (n=299)
Male	44% (n=88)	42.5% (n=130)	56% (n=14)	43.7% (n=232)
Race % (n)				
African American	40% (n=80)	35.9% (n=110)	36% (n=9)	37.5% (n=199)
Caucasian	11.5% (n=23)	10.0% (n=52)	.08% (n=2)	14.5% (n=77)
Hispanic	32.0% (n=64)	33.0% (n=101)	52% (n=13)	33.5% (n=178)
Polish	3.5% (n=7)	4.9% (n=15)	0% (n=0)	4.1% (n=22)
Asian	1.5% (n=3)	3.5% (n=11)	0% (n=0)	2.6% (n=14)
Other	11.5% (n=23)	5.6% (n=17)	.04% (n=1)	7.7% (n=41)
Marital Status % (n)				
Single	38.5% (n=77)	38.6% (n=118)	24% (n=6)	37.9% (n=201)
Married	46.05 (n=92)	44.1% (n=135)	52% (n=13)	45.2% (n=240)
Divorced	6.0% (n=12)	9.5% (n=29)	12% (n=3)	8.3% (n=44)
Widowed	19.5% (n=19)	7.8% (n=24)	12% (n=3)	8.7% (n=46)
Years Diabetic Mean (SD)				5.62 (2.92)
HbA1C Mean (SD)				7.42 (1.45)
Foot Exam by Provider % (n)				
Foot Exam	0% (n=0)	62% (n=191)	76% (n=19)	42.0% (n=223)
No Foot Exam	100% (n=200)	38% (n=115)	24% (n=6)	57.8% (n=307)
Monofilament Tool Score Mean				1.68 (.816)

(SD)

Referral to  
Podiatry % (n)

Referral	68% (n=136)	27% (n=82)	20% (n=5)	41.8% (n=223)
No Referral	32% (n=64)	73% (n=224)	80% (n=20)	57.6 % (n=308)

Single Limb  
Amputation % (n)

Amputation	2.5% (n=5)	0% (n=0)	0% = (n=0)	0.9% (n=5)
No Amputation	97.5% (n=195)	100% (n=100)	25% (n=25)	99.1% (n=526)

Provider Type %  
(n)

Physician	60.5% (n=121)	53.6% (n=164)	60% (n=15)	56.5 % (n=300)
Nurse Practitioner	39.5% (n=79)	46.4% (n=142)	40% (n=10)	43.5% (n=231)

Insurance  
Type % (n)

Self- Pay	24.5% (n=49)	34.6% (n=106)	40% (n=10)	43.5% (n=231)
Medicaid	42.5% (n=85)	34.0% (n=104)	32% (n= 8)	37.1 % (n=197)
Medicare	24.0% (n=48)	22.9 (n=70)	16% (n=4)	23.0% (n=122)
Private Insurance	9.0% = (n=18)	8.5% (n=26)	12.% (n=3)	8.9% (n=47)

Total	200	306	25	531
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A total of 531 patient participants were included in this EBP project practice change. Weekly audits were obtained. Data outcomes can be viewed in (Figure 4.2 and Table 4.2). There was no statistical difference between the pre-intervention, intervention and post-intervention groups due to attrition, as there was no change in participation.

The ages of patient participants ranged from 18-74 with an average age of 53.77 years and a SD of 12.19 years. There were 299 (56.3%) female participants compared to 232 (43.7%) male participants (Figure 4.3). The sample was primarily African American with 199 (37.5%) participants, followed closely by 178 (33.5%) Hispanic participants. The rest of the sample was 14.5% Caucasian, 4.1% Polish, 2.6% Asian and 7.7% Other (Figure 4.4).

The characteristics of participants regarding marital status indicated that 201 (37.9%) of participants were single, 240 (42.05%) of participants were married, 44 (8.3%) were divorced, and 46 (8.7%) were widowed (Table 4.1). A clinical foot exam by the provider was completed in 224 (42.2%) instances and was omitted by providers 307 (67.9%) times. Referral to podiatry for 224 (42.2%) while 307 (57.8%) patients were not referred. Patients with a history of single limb amputation were represented by 6 (0.9%) participants. More patients were evaluated by physician providers at 300 (56.5%) while 231 (43.5%) patients were evaluated by a nurse practitioner (see Figure 4.6). The most frequently reported insurance type was Medicaid at 197 (37.1%) followed by self-pay at 165 (31.1%), Medicare at 122 (23.0%) and private insurance at 47 (8.9%) (Figure 4.6).

Figure 4.2 *Weekly Outcome Data*

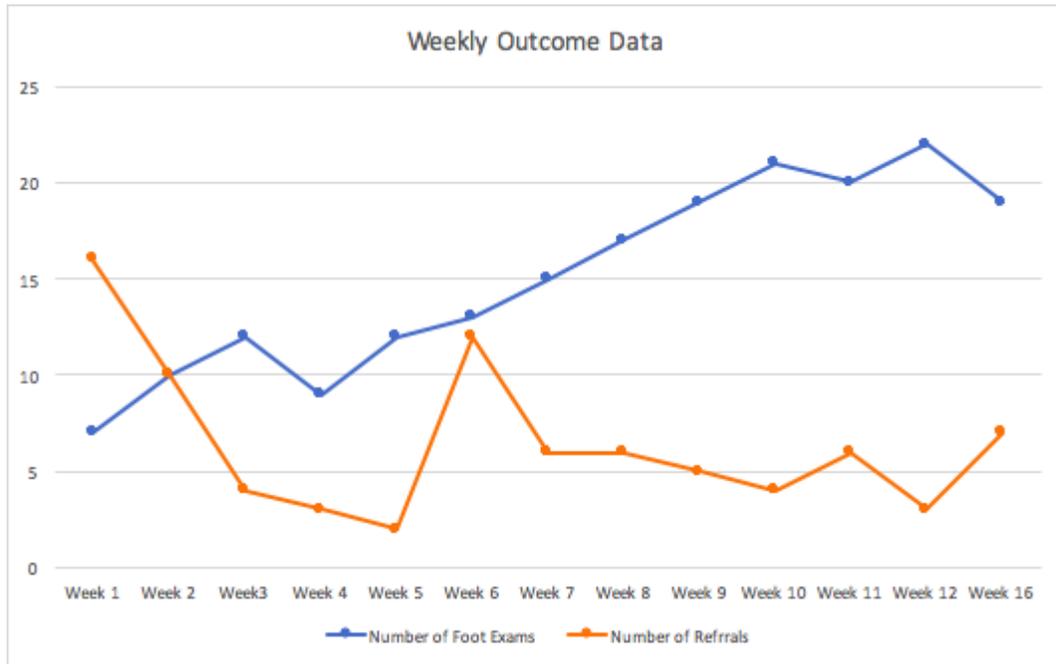


Table 4.2

*Weekly Intervention Provider Foot Exam Compliance*

Week	Yes % (n)	No % (n)
1	28% (7)	72% (18)
2	40% (10)	60% (15)
3	48% (12)	52% (13)
4	36% (9)	64% (16)
5	48% (12)	52% (13)
6	52% (13)	48% (12)
7	60% (15)	40% (10)
8	68% (17)	32% (8)
9	76% (19)	24% (6)
10	84% (21)	16% (4)
11	80% (20)	20% (5)
12	88% (22)	12% (3)
16	76% (19)	24% (6)

Figure 4.3 Participant Gender

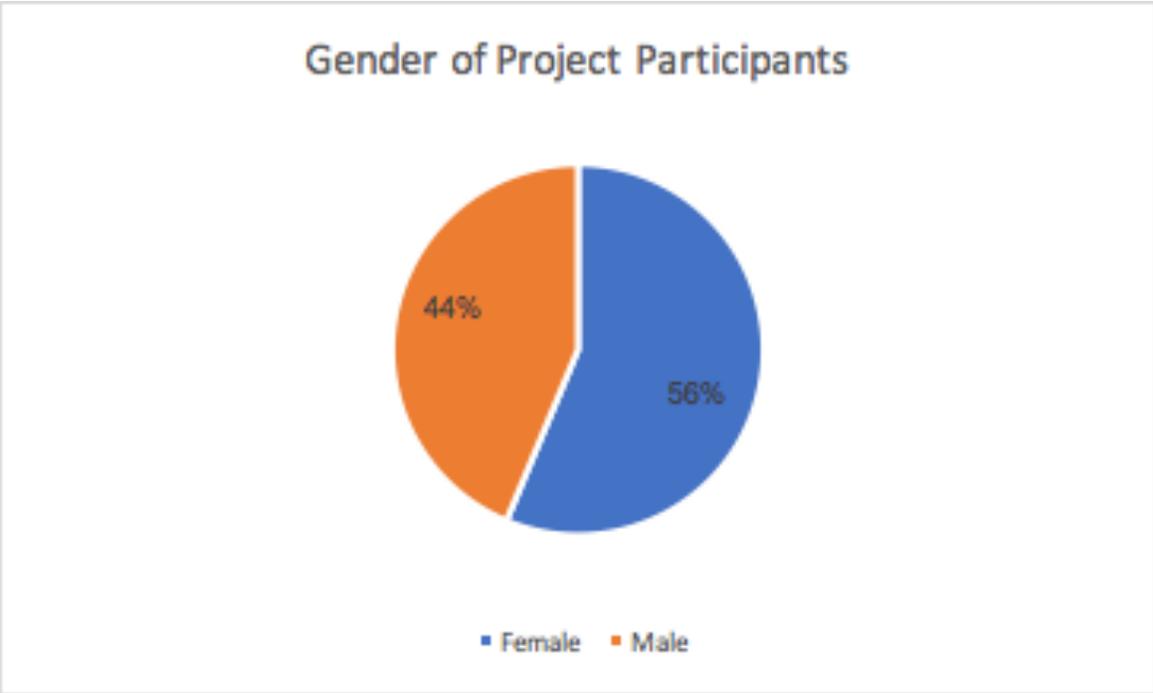


Figure 4.4. Ethnicity of Patient Participants

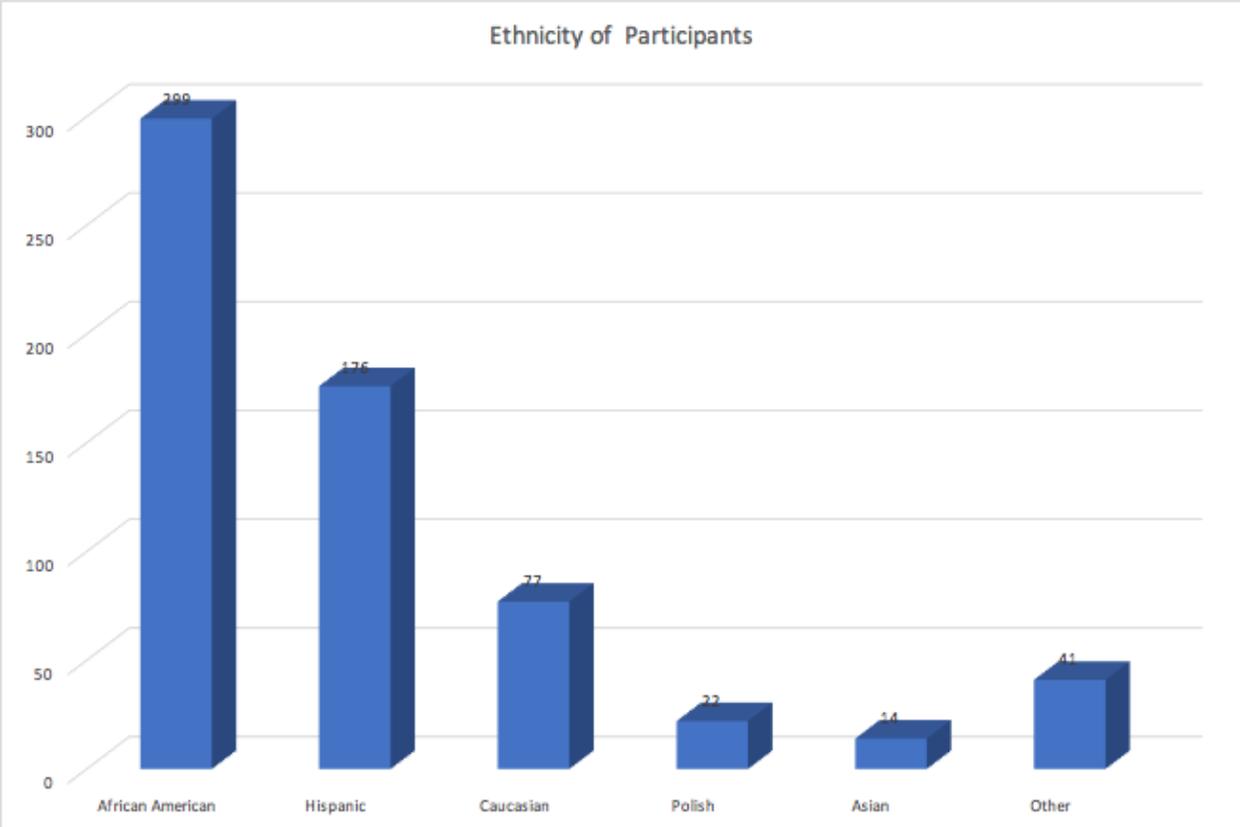


Figure 4.5 Participant Marital Status

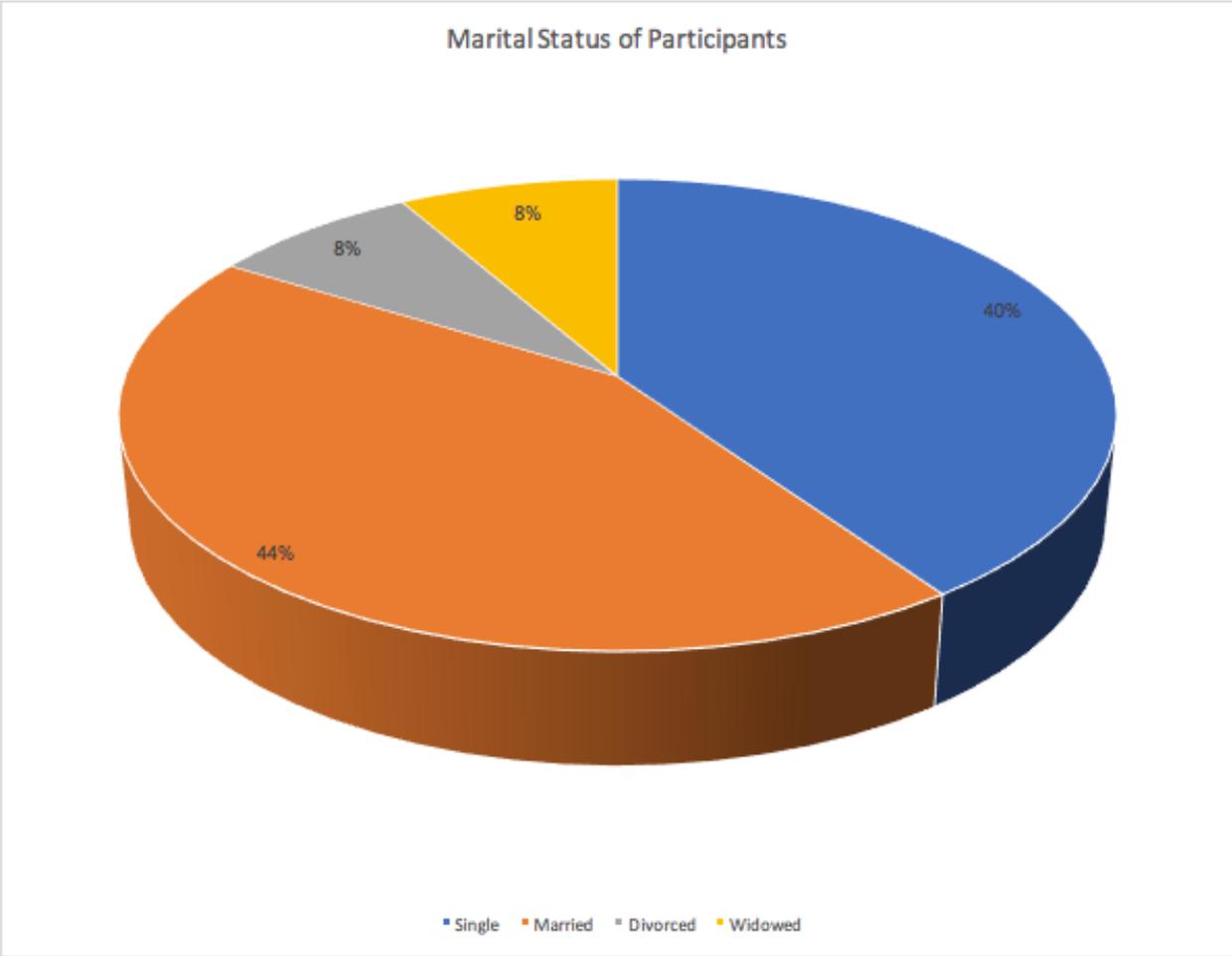
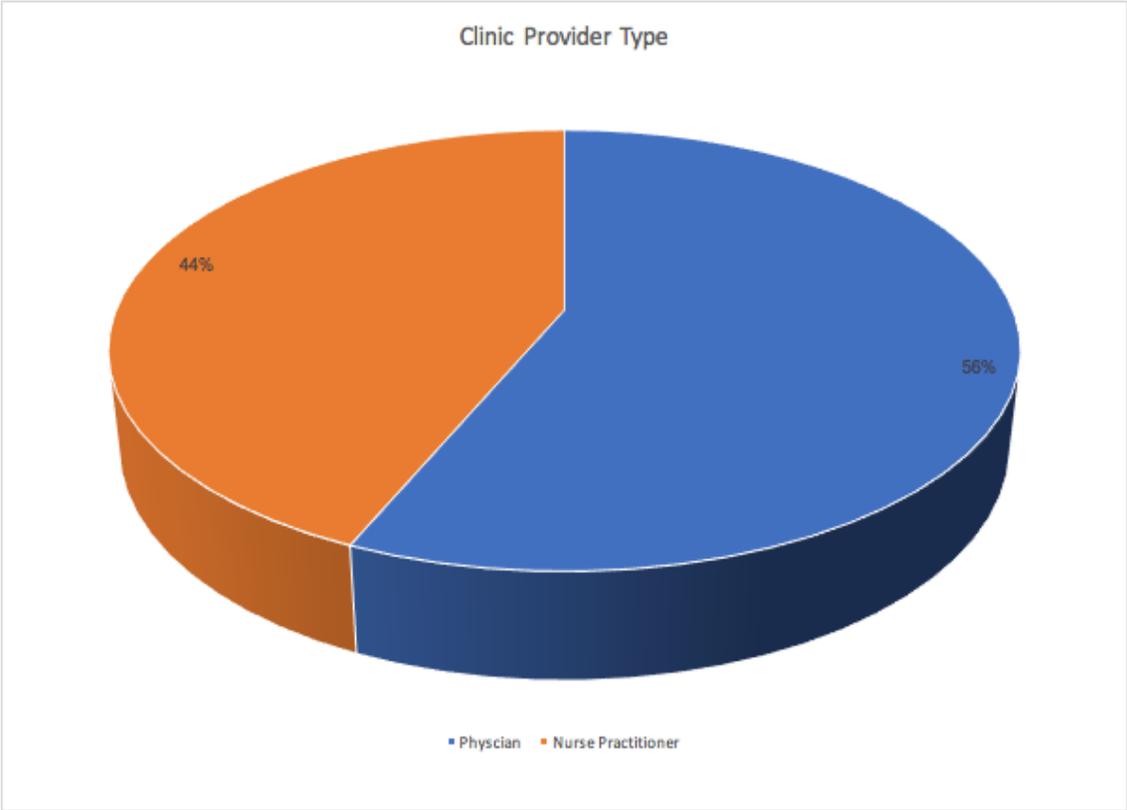


Figure 4.6 Participant Provider Type



## Changes in Outcomes

### Statistical Testing and Significance

The primary outcome for this EBP project was appropriate referral to podiatry clinic. Data analysis was completed using SPSS version 22. Findings show that there were improvements in the number of appropriate referrals between the pre-intervention group and the intervention group and continued improvement from the intervention group to the post intervention group. The secondary outcomes that were examined include provider assessment and patient follow-up referral appointment compliance.

### Primary Outcome: Appropriate Referrals

The primary outcome for this EBP project was appropriate referral. A two by two table was constructed for the appropriate referral group versus all other groups and whether a referral was made. A chi square test of independence was performed and showed statistical evidence of an association between an appropriate referral and receiving a referral ( $X^2(1) = 72.657; p < .001$ ) (Table 4.3). The relative risk of receiving a referral given a patient was in the high-risk group with an SWM tool score of three (Semmes, J., Weinstein, S., Ghent, L., & Teuber, H.-L., 1960) was 20. In other words, those in the highest risk group as defined by a SWM tool score of three were 20 times more likely to get a referral compared to those scoring a zero, one or two on the SWM tool score scale (Semmes et al., 1960).

During the pre-intervention phase, the SWM tool was not yet available in the EBP project clinic site for provider use to complete diabetic foot risk assessment; therefore, no SWM tool assessment data are available for the pre-intervention group. During the pre-intervention phase 68% (n = 136) patient participants received a podiatry clinic referral without having had a provider foot risk assessment with provider use of the SWM tool.

In the intervention phase, provider use of the SWM tool was introduced and implemented. Data showed that there was a total of 27% (n = 82) intervention patient participants and there were 20% (n = 5) post-intervention patient participants who received a

Table 4.3

*Referral to Podiatry Chi Square Tests*

	<i>Value</i>	<i>df</i>	<i>Asymp. Sig. (2-sided)</i>
Pearson Chi Square	72.657	3	.000

referral to the podiatry clinic based on the SWM tool score (Table 4.4). SWM tool scores for the intervention and post-intervention groups ranged from 0 to 3 (Table 4.5). Although the total number of referrals decreased from the pre-intervention phase to the intervention group, it is expected that those participants in receipt of a referral after having had a provider foot risk assessment were more appropriate.

### **Secondary Outcome: Provider Assessment**

A secondary outcome for this EBP project focused on provider assessment of diabetic foot risk. Two 2x2 tables were constructed for performance assessment and group (pre-intervention vs intervention period and pre-intervention vs post-intervention periods). A *Chi* square test of independence and relative risk calculations were carried out for each table to assess whether the group was associated with providers completing the exam. There was evidence of an association ( $\chi^2(1) = 93.209$ ;  $p < .001$ ) between providers performing an exam and whether a patient was seen in the pre-intervention or intervention period (Table 4.6).

During the pre-intervention phase, chart audit revealed that no provider foot risk assessments were performed by providers. Additionally, the SWM tool had not yet been introduced for provider use to complete diabetic foot risk assessment at the EBP project clinic site. During the pre-intervention phase 0% ( $n = 0$ ) patient participants received a provider foot risk assessment.

In the intervention phase, provider use of the SWM tool was introduced and implemented. Data showed that there was a total of 62% ( $n = 191$ ) intervention patient participants and there were 76% ( $n = 19$ ) post-intervention patient participants who received a provider foot risk assessment with provider use of the SWM tool (Table 4.7).

When the same analysis was completed for the pre-intervention vs. the post-intervention group, statistical evidence of an association. between the time a group was seen (pre-intervention vs post intervention) and whether a patient received an exam ( $\chi^2(1) = 88.7014$ ;

Table 4.4

*Referral to Podiatry*

Variable	Pre-Intervention % (n=200)	Intervention % (n=306)	Post-Intervention % (n=25)	Total % (n=531)
Referral	68% (n=136)	27% (n=82)	20% (n=5)	42% (n=223)
No Referral	32% (n=64)	73% (n=224)	80% (n=20)	58% (n=308)

Table 4.5

*Semmes Weinstein Monofilament Tool Scores*

Variable	Intervention % (n =192)	Post-Intervention % (n = 19)	Total % (n = 211)
Score of 0	9% (n=18)	0% (n=0)	9% (n=18)
Score of 1	29% (n=55)	26% (n=5)	28% (n= 60)
Score of 2	48% (n=93)	57% (n=11)	49% (n= 104)
Score of 3	14% (n=26)	16% (n =3)	14% (n=29)

Table 4.6

*Provider Foot Assessment Chi Square Test*

	Value	df	Asymp.Sig. (2-sided)
Pearson Chi-Square	93.209	2	.000

Table 4.7

*Provider Foot Assessment*

Variable	Pre-Intervention % (n = 200)	Intervention % (n = 306)	Post Intervention % (n = 25)	Total % (n = 531)
Completed Foot Exam	0% (0)	62% (191)	76% (19)	42% (210)
Not Completed Foot Exam	100% (200)	38% (115)	24% (6)	58% (321)

$p < .001$ ) (Table 4.8). Patients in the post-intervention period were 11 times as likely to get an exam as patients in the pre-intervention period.

### **Secondary Outcome: Patient Follow Up Compliance**

Another secondary outcome of this EBP project was the rate of patient follow-up compliance with referral to PC. An analysis of whether an exam was performed and patient compliance with a podiatry referral was conducted. Two by two tables were constructed for a subset of patients scoring zero, one, or two on the SWM tool scoring scale and a separate table for those scoring three on the SWM tool scale. Seventy-one percent of patients receiving an assessment kept their podiatry referral appointments (Table 4.9). Another way of interpreting this is about twice as many patients (71% vs 29%) who received an assessment kept their podiatry referral appointments.

In patients scoring zero, one or two on the SWM tool scoring scale, there was not statistical evidence of an association between assessment and compliance with a podiatric referral ( $X^2(1) = 6.081; p = .014$ ). This is compared to almost four times as many (79% vs 21%) of those patients who scored a three on the SWM tool scoring scale. A clinically important difference. Unfortunately, due to sparse cells the relationship between whether patients receiving an assessment and patient compliance with podiatry referral could not be assessed for statistical evidence. Due to a coronavirus pandemic, the time data could be collected for this outcome was limited. Therefore, only 191 of the 306 patients could be assessed. Of these, 43% ( $n = 82$ ) received an appropriate referral to podiatry. Seventy-one percent ( $n = 58$ ) of the patients who were appropriately referred kept their scheduled appointment in the PC.

### **Instrument Reliability and Validity**

Instruments must be tested for reliability before determining validity (Cronk, 2018). There was no formal tool used for data collection. The data collection tool was created by the PL and was basic and straightforward.

Table 4.8

*Provider Foot Assessment Chi Square Test*

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	Value	df	Asymp.Sig. (2-sided)
Pearson Chi-Square	88.7014	2	.000

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Table 4.9

*Patient Follow-up Compliance*

Variable	Intervention (n=82)	Post-Intervention (n=5)	Total
Compliance	71% (n=58)	*	•
Non-Compliant	29% (n=24)	*	*

## CHAPTER 5

### DISCUSSION

The provision of diabetic foot assessment is paramount in the delivery of diabetes care. PCPs are in an ideal position to provide early diabetic foot risk assessment and referral to appropriate intervention as indicated as a regular part of the diabetic patient's primary care visit. This project was implemented at a large outpatient general medicine clinic in the Midwestern region of the United States. This EBP project answered the following compelling PICOT question: "In adult diabetic patients ages 18-74 seen in the primary care setting, does a multi-faceted intervention, compared to previous clinic foot practices, result in referrals that are more appropriate, improved provider assessment, and increased patient compliance with follow-up appointments over a 12-week period?" The evidence-based multi-faceted intervention included: (a) implementing provider history and foot physical assessment including the use of the Semmes Weinstein Monofilament (SWM) tool to assess for actual diabetic foot complication, (b) assessing of footwear, (c) providing patient education, (d) multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback. Project findings, including successes and limitations will be disseminated in this chapter. The EBP project model, The Iowa Model Revised, 2017 (Iowa Model Collaborative, 2017) was used to guide this project and will be discussed as well the implications for future research on this same or similar topic.

#### Explanation of Findings

Prior to the implementation of this EBP project, the primary care provided at the EBP project site did not include diabetic foot risk assessment. The PL, in collaboration with leadership, worked diligently to implement an evidence-based foot risk assessment workflow into the primary care setting which incorporated provider history and foot physical assessment including the use of the SWM tool to assess for actual diabetic foot complication as well the implementation of other best practice interventions identified in the literature. The primary

outcome for this EBP project was designed to answer the clinical question concerned with appropriate referrals. Data were also collected for secondary outcomes to determine provider assessment and patient compliance with follow-up to PC appointments.

### **Primary Outcome: Appropriate Referral**

Feng and colleagues (2011) assert that the SWM tool has significant predictive power as a screening tool for patients with diabetes in clinical settings. Physicians often use the SWM tool as a noninvasive, low cost, rapid, and easy to apply test to identify patients at high risk for ulceration or amputation (Feng et al., 2011). For this project, data analysis revealed that there was a statistically significant increase in the number of appropriate referrals ( $\chi^2(1) = 72.657; p = < 0.001$ ) indicating that use of the SWM tool promoted more appropriate referrals to the PC. Overall, 27% (N = 82) of the 306 intervention patients were appropriately referred. A calculated risk ratio showed those with a SWM score of 3 were 20 times more likely to get a referral compared to those scoring a 0, 1 or 2 on the SWM scale. These findings are congruent with findings from a study by Feng et al. (2011) who concluded that the SWIM test is a significant and independent predictor of future foot ulceration or likely of future LEA in patients with DM. With negative results, they found that 2.5% to 10.7% had the absolute risk of developing an ulcer while positive SWM results were consistent with 12.4% to 38.6% of risk for the development of a foot ulcer. Assessment with the SWM is an important evidence-based assessment for the early detection of diabetic foot complication leading to improved patient selection for early intervention or management.

There are many factors that contributed to more appropriate referrals. Change in practice relies not only on the nature and strength of the evidence, but also on the practice environment in which the process is facilitated (Kueny, A., Shever, L., Macklin, M., & Titler, M., 2015). Prior to the implementation of this project, essentially no foot assessments were being completed by PCPs at the EBP project clinic site. Instead, patients were simply being referred directly to Podiatry without baseline assessment. As a result of this inappropriate referral

practice, the PC clinicians became very overwhelmed and experienced extreme difficulty with the managing care for patients backlogged in the queue to be seen. Leadership verbalized a commitment to improving diabetic foot care services at the EBP clinic site resulting in the formation of this EBP project. The pre-intervention foot risk assessment baseline was 0% thus, any foot risk assessments completed by providers as a result of implementation would be an improvement.

Podiatry specialty care providers created an online provider foot risk assessment tutorial for clinician use to assist in the provision of provider education and competence. The PL was instrumental in disseminating the tutorial link to Team A clinicians for use and additionally providing consistent reminders encouraging providers to view the tutorial. Additionally, the PL served as a resource to many clinicians who had questions or concerns on SWM tool use technique or scoring inquiries. This resource was very instrumental in ensuring providers were competent and consistently performing foot risk assessment in the correct manner. Engaging clinicians in the process of change through the availability of resources to improve the provision of care not only prepares clinicians to do and be at their best but it empowers them to implement recommended best practice changes with decreased resistance.

Patient education promotes patient centered care and increases adherence. The PL created a basic trifold patient self-care foot education pamphlet for patients to use as a reference in the provision of self-care at home. Team A clinicians and ancillary staff attached the educational pamphlet as part of the patient discharge process to include a brief overview of the pamphlet content. Sharoni et al. (2016) assert that various strategies in health education such as foot assessments, verbal and written instruction, discussion, counseling, problem solving, social support, home visits, and phone calls have all been shown to significantly improve the effect of education programs and overall patient outcomes.

Feedback contributes significantly when developing learners' competence and confidence at all stages of their professional career. Providing feedback helps PCPs to think

about the gap between actual and desired performance and to identify ways to narrow the gap and improve (Hardavella et al., 2017). Feedback was very instrumental to the success of the implementation of this EBP project. This project took place over the course of 12 weeks. During the first 6 weeks, data about referral rates were not shared with providers due to PL oversight. Beginning with week 7, the PL provided numerical feedback related to the number of foot assessments and the number of referrals to Team A project participants with a noted change in weekly outcome performance numbers. Figure 4.1 shows the trend of weekly provider foot assessments and the number of weekly referrals. Over weeks 7 through 12 the number of foot exams regularly improved.

### **Secondary Outcomes**

**Provider assessment.** In 2018, data from the site facility showed that < 20% of patients received foot risk assessments by providers (CMAPP, 2018). Before a provider can make an appropriate referral, it is necessary that a thorough assessment is conducted. For this project, data analysis revealed that there was a statistically significant association between provider assessment and whether a patient was in the pre-intervention or intervention group ( $\chi^2(1) = 93.209; p < .001$ ). Additionally, there was an association between provider assessment and whether a patient was in the pre-intervention or post-intervention group ( $\chi^2(1) = 88.7014; p < .001$ ). Intervention patients were 9 times more likely to be assessed than pre-intervention patients. Post-intervention patients were 11 times more likely to be assessed than pre-intervention patients. As a result of this project, the percentage of diabetic patients receiving an assessment increased to 191 (62%) of the 306 intervention patients.

Serious diabetic foot complications can be delayed and even prevented with appropriate, careful, and reliable screening and management standards (Formosa et al., 2016). Reasons for the increased number of diabetic patients receiving a foot risk assessment likely includes the PL's multifaceted implementation of the SWM tool use into primary care and organizational

leaderships support and collaborative provision of clinician education and mandated clinician viewing of the video tutorial featuring proper diabetic foot care technique.

**Patient follow-up compliance.** Patient compliance is a strong indicator of the care patients receive. Evidence shows that the approach the provider uses, their “counseling style,” can foster, diminish, or wither patient adherence to recommendations (Gabbay, Kual, Ulbrecht, Sheffler, and Armstrong, 2011). Taking the time to provide foot risk assessment, assess the footwear, review of the foot self-care pamphlet and allowing time for the patient to ask questions is likely the reason for a noted increase in adherence. For this project, data analysis revealed that about 70% (n = 57) of the intervention patients who received a foot assessment attended the podiatry specialty clinic appointment versus the 30% (n = 41) patients who kept their appointments in the pre-intervention group.

These findings are congruent with van Acker and colleagues (2014) who found that care and follow-up of patients with foot risk using multidisciplinary consultation was effective not only in curative treatment but also in primary and secondary prevention followed by reduction in major amputations associated with diabetic foot. Increasing patient compliance with follow up to specialty clinics after referral may have been effective because the multidisciplinary approach offers the added layer of regimen reinforcement thus having a higher likelihood of increasing a patient's level of compliance while decreasing their risk for foot complication.

### **EBP Framework**

The PL used The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) to guide the implementation of this EBP project. The steps in the Iowa Model Revised include identifying the triggering issues and opportunities, stating the question or purpose, prioritizing the topic, forming a team, assembling, appraising and synthesizing a body of evidence, determining if there is enough evidence, designing and piloting the practice change, determining project appropriateness for adoption,

integrating and sustaining the project change, and disseminating the results (Iowa Model Collaborative, 2017).

The Iowa Model Revised (Iowa Model Revised, 2017) was applicable to this EBP project because it assisted the PL with translating research findings into clinical practice through use of the models' structured step by step algorithm design. Lack of diabetic foot risk assessment in the primary care setting was the triggering issue identified by both the PL and senior leadership at the EBP project clinical site. It was determined by leadership that early identification of diabetic patients who have high risk for actual diabetic foot complication proved to be more cost effective than the expense related to frequent emergency room encounters, prolonged hospitalizations and or the necessity for patients to undergo amputation surgical procedures due to diabetic foot complications. The purpose of the project was established and as part of the second stage of the model, a PICOT question was developed.

In the third stage of the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) details the priority of the topic. Implementing the provision of foot care services by providers into primary care was discussed with leadership. In 2018, of the approximate 59,000 patients who received clinical care services at the EBP project clinic site, the internal census database identified 18,221 of them as being diagnosed with DM. Review of internal statistical data further revealed that less than 20% of the diabetic patients seen in this clinic setting had documented foot exams in the EMR (CMAPP, 2018). Additionally, it was determined that PCPs were simply referring patients to podiatry via the EMR without providing a baseline foot assessment to determine appropriate need for the referral. Feedback from leadership revealed that this practice created a tremendous backlog in the availability of PC appointments. Lack of assessment and inappropriate use of the referral system were the catalysts which sparked the vision and set the priority for the leadership to commit to seeking a change in practice aimed at improving the foot care services for patients with diabetes in primary care. Improving diabetic foot care services was set as a priority by the

organization and the PL was given the green light to begin reviewing the literature to determine best practice for incorporating provider foot assessment into primary care.

In the fourth stage of the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) the PL formed a team consisting of Team A physicians, nurse practitioners, registered nurses, medical assistants, a team clerk and senior leadership. The clinic layout configuration is split into teams so in essence, the team structure was already in place prior to this EBP project. The PL is a member of Team A; therefore, the decision was made to initiate project implementation in this section of the clinic. In addition to the clinicians and ancillary staff on Team A, other group members that comprised the team included risk management, facility leadership and committee members, specialty PC clinicians and information technology personnel.

Stage five of the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) involved assembling, appraising and synthesizing a body of evidence. The PL conducted a literature search in an effort to determine best practice recommendations for the project. The PL assembled, appraised and synthesized the evidence to determine best practice recommendations for this EBP project. In the sixth stage, data from the project site, and evidence from the literature were reviewed and it was determined that there was sufficient evidence to implement a practice change.

Designing and piloting the practice change in stage seven of the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) proved to be very challenging. Regularly attending organizational meetings focused on diabetes care, obtaining IRB approval for the project, ordering supplies for the project, developing a team workflow, developing patient foot self-care education, initiating the introduction of staff education related to foot care assessment, and providing ongoing feedback was an arduous task. The PL worked closely with the team to develop, implement, and evaluate a workflow aimed at facilitating the incorporation of provider foot risk assessment into daily

practice. Modifications were made to the workflow algorithm to assist in streamlining the tasks associated with incorporating provider foot assessments into primary care in an effort to maintain the feasibility at the EBP project site. Stages eight and nine of the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care, which includes determining project appropriateness for adoption and integrating and sustaining the practice change.

The final stage of the model is the dissemination of the results. A variety of approaches are available for the dissemination of project findings. Team A is considered the pilot site for foot risk assessment for this organization. Project results for each of the measured outcomes were found to be statistically significant and therefore, are being considered by leadership for use across the healthcare system. Until a formal decision is made, upon obtaining leadership approval, the PL will plan to share the EBP project poster board results at the staff huddle as it will serve as a visual guide to the numerical data outcome results. For research results to reach the widest audience, it must be published in a journal. The gold standard is a peer reviewed journal that is indexed by the National Library of Medicine and other abstracting or indexing services since this will ensure that everyone conducting a literature search will be able to locate the data (Edwards, 2015). The PL will consider this dissemination option.

A strength of the Iowa Model Revised (Iowa Model Collaborative, 2017) is that the model is easy to follow making feasibility of use from novice to expert a streamlined process. Use of the model promotes quality improvement as it allows organizations to prioritize willing moving towards improving patient outcomes. Another strength of this EBP project was its relevance. Incorporating the provision of diabetic foot care into a primary care clinic that sees an average of 58,000 diabetic patients annually was an ideal setting. Lastly, use of the workflow algorithm that was developed by the PL and working with the staff to modify when indicated made completing a foot assessment during a primary care clinic encounter a seamless process.

A weakness to this model is that it is not designed for individual use; therefore, a single clinician would not be successful at implementing change in an organization using this model. The model does not make provisions for organizational potential barriers such as budget delays, culture differences or resistance to change, that may arise during the implementation process. Additionally, the model does not have a step included for data collection methods which can potentially cause ambiguity on proper data collection procedure.

In summary, the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) was an effective and well suited framework to guide this EBP project because the model provided a user friendly step by step approach to the identification, prioritization, appraisal, implementation, integration, sustainability, and evolution of this EBP project. The model promotes team collaboration and dissemination of best practice recommendations to enhance patient outcomes.

### **Strengths and Limitations of the DNP Project**

Over the course of the 12 weeks designated for the implementation of this EBP project, there were several factors that impacted project outcomes that can be categorized as strengths or limitations. Evaluation of outcomes has allowed the PL to revisit design and implementation decisions that may serve as the basis for future research.

#### **Strengths**

Support from organizational leadership was a strength. Senior leadership had a vision to improve diabetic foot care services at this EBP clinic site and assisted in both mandating and mobilizing staff participation. Leadership made diabetic foot care a priority not just for the clinic and team but for the organization. Diabetes specific updates were provided weekly and the PL was granted access to regular HEDIS meeting attendance, webinars, quarterly division meetings and organizational email communications focused on diabetes foot care, Leadership support for a specific change and participant willingness to engage in change may be dependently related to the success of implementing a new strategy (Caldwell et al., 2017).

To promote diabetes awareness and improve diabetes foot care quality, the PL worked diligently at gaining budget approval for SWM tool supplies and initiating clinician foot assessment education training via use of the video tutorial. The PL utilized daily huddle time to provider reminders and to impart the importance of provider compliance with foot assessment, documentation, and billing. Additionally, the daily huddle served as a platform for the PL to provide ongoing feedback to clinician project participants over the course of the 12-week implementation of this EBP project.

Timing and relevance of this project can also be considered a strength. This EBP project came at a time when organizational leadership was seeking to enhance care for patients who are diagnosed with DM. Incorporating provider foot assessments into primary care while striving to meet and exceed the benchmarks set by HEDIS for diabetes care nationally proved to be an excellent collaborative process for all involved. Feasibility of incorporating foot assessment in the primary care setting seems to have caused little disruption to the current clinic workflow and therefore, very little resistance to practice change was invoked by clinic staff to the PL and leadership's plan to change practice.

Another strength of this EBP project was the development, initiation, implementation, and maintenance of basic diabetes foot self-care education for patient and PCP participants. Incorporating the use of Interactive behavioral changing patient education strategies into primary care to support diabetes self-care management and chip away at some of the most daunting barriers to diabetes self-care that exist (Piette, 2007). Improved self-care behaviors may likely positively influence patient medication regimen and follow-up compliance. The PL developed a basic foot self-care education pamphlet (Appendix F), a reminder foot assessment tip sheet ID badge card (Appendix B), and initiated the video training process for staff to view a foot assessment tutorial aimed at teaching the proper technique to use when performing foot assessment.

Providing on-going feedback is critical to successful implementation during the change process (van Acker et al., 2014). This is especially evident in this project when one looks at the data (Figure 4.2). It is interesting to note that during weeks 1-5 to weeks, the PL overlooked providing data about HCP compliance with assessment and referral. During that time, these rates were between 28% -48%. However, during weeks 6-12 performance feedback was provided weekly to Team A, and over those weeks one can see that rates of assessment and referral steadily increased. The rates during this time frame ranged between 58%-88%. The trends in these data show how important ongoing feedback was to successfully meet project outcomes (Table 4.2).

Another strength of the project would be the large sample size used to evaluate outcomes (N = 531). Having this large sample size may help to generalize outcome findings for this project. Future projects utilizing the same or similar sample size to replicate outcomes may support this theory.

Lastly, another strength present throughout this EBP project process was the presence of strong support from both the faculty advisor and the EBP project site facilitator who guided the PL relentlessly to the close of this EBP project process. Additionally, IRB exemption from both the project site and university was obtained without delay.

### **Limitations**

The main limitation to this EBP project was time. The short 12-week time frame for the project impacted data collection and evaluation. While this EBP project was implemented over the course of 12-weeks, turnaround time from the point of referral to assigned appointment to follow up was often prolonged. In some instances, this turnaround time period span was anywhere from 30-45 days. This timeframe created a delay in the PL's ability to audit charts for compliance of measured outcomes. Additionally, due to worldwide concern for COVID 19, and the mandated order for social distancing, project data collection and outcomes had to be abruptly halted which hindered post-intervention data collection related to follow up compliance.

Most often, workflows are looked at in isolation and the processes appear quite logical (and even efficient) in acting to accomplish the end goal. It is in the interaction among these processes that complexities arise (Cain & Haque, 2016). Organizational limitations for this EBP project included budget approval and delivery delay for EBP project supplies. The EBP project clinical site is located within a public teaching facility funded by the government. Even after gaining leadership approval for ordering the monofilaments, the PL endured many untimely and often unexplained roadblocks before the SWM tools were actually delivered to the clinic for provider use.

Collecting data about the outcome of appropriate referral was challenging. For this project, appropriate referral is defined as a SWM tool score of 3 and “yes” to referral, which is consistent with the literature. However, some patients who earned a SMW score of 0-2 were referred to the podiatry clinical for other reasons. These reasons included problems such as places of skin breakdown on the foot, need for nail care, or callus care maintenance. Therefore, the high percentage of patients who were referred for follow-up even though they did not have a problem with peripheral neuropathy can likely be attributed to these diabetic foot care interventions. Exceptions to the referral criteria for these patients caused a shift in the measured outcomes data for appropriate referral.

### **Implications for the Future Practice**

There are implications that can be made as a result of this EBP project. Recommendations regarding practice, theory, research and education are important to consider when strategizing ways to propose or sustain evidence-based practice changes for the future. This EBP project implemented an evidence based multi-faceted approach to the provision of provider diabetic foot risk assessment into primary care.

### **Practice**

The lifetime risk of a person with diabetes developing a foot ulcer may be as high as high 25% (Boulton et al., 2008). PCPs are in an ideal position to provide diabetic foot risk

assessment in the primary care setting. Frequency of PCPs performing a patient foot risk assessment will depend on the SWM tool score. This EBP project has demonstrated that incorporating an evidence-based practice provider foot assessment intervention into primary care can be successfully achieved by following the steps outlined in the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017). Implementing such a workflow was shown to have caused minimal disruption in the clinical setting. Furthermore, sustainability of the project is expected, as the organization plans to expand the workflow to other clinics. As the intervention is adopted into practice, current and new staff will continue to be educated on the workflow algorithm and components of care.

For years, US areas have experienced shortages of PCPs. Nurse practitioners are actively helping to reduce this shortage (Ortiz et al., 2018). The FNP can contribute to the foot care needs of diabetic patients seen in the primary care setting by adhering to best practice recommendations, educating patients and families about foot self-care, initiating appropriate referrals to specialty based on tool assessment scores, documenting assessments, and encouraging patient compliance to follow-up visits.

### **Theory**

Theoretical frameworks provide a systematic approach to translating evidence into practice. The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Iowa Model Collaborative, 2017) was used to guide this project implementation. This model provided a systematic framework for the PL and team providers to follow as they navigated uncharted territory when taking on the decision to change practice. The findings from this EBP project influence future development by promoting the incorporation of provider foot risk assessment in primary care into other clinic sites across the organization. This EBP project, grounded in health promotion, safety, and preventive health, sought to improve patient outcomes through changed behavior care practices.

### **Research**

Future research can be focused on PCP adherence to foot risk assessment in the primary care setting. Additional research regarding correlations between provider assessment and documentation should also be undertaken to determine consistency in practice. Strategies that focus on clinical practice guidelines to specifically address foot risk assessment in primary care should be further developed. Studies focusing on variations of workflow algorithms such as the workflow chart developed by the PL for this EBP project should be undertaken to mitigate clinic routine disruption and risk for staff resistance when implementing change. Additional research regarding best practice modes of education for both patients and staff which focus on literacy level should be undertaken to design a variation of educational modes that can successfully be used to reach intended audiences that include differing literacy levels. Primary care is the ideal setting to incorporate foot assessment into general care follow up visits. Efforts aimed at examining quality of life and with a focus on closing the gap between primary care, diabetes and podiatry should be undertaken as they will serve to reduce the risk for foot complication.

### **Education**

There is a need for increased education about provider foot assessment in primary care. Clinicians in primary care are at the forefront, often encountering patients more regularly than specialty care providers. To that end, providers need to be educated regarding the provision of diabetic foot self-care and foot assessment as it is essential to promoting favorable outcomes for diabetic patients. For this EBP project, providers were educated through use of a short video tutorial, pocket tip sheet, and verbal reminders and cues. A review of the literature has demonstrated other modes of education could include use of PowerPoint, face to face in-service, group education, brochures, computer modules, teach back, scripting, and use of apps (Sharoni et al., 2016). It is critical to determine best practice and to implement its use to provide educational resources to those implementing the practice change. Education should exceed

simply focusing on the clinical problem by including the development of preventative strategies, goal setting and steps to take with abnormal findings.

In addition to HCP education, it is essential to educate patients. Interventions to improve self-care have led to documented improvements in self-efficacy (Paterick, T., Patel, N., Tajik, J., & Chandraekaran, K., 2017). The PL developed a basic patient foot self-care education pamphlet designed to provide a brief overview of the important facets related to foot care. While no formal patient feedback was collected, the PL did receive messages of appreciation for the foot pamphlet and the explained importance of regular self-care foot education. The PL developed the patient self-care foot pamphlet that was disseminated to patients at discharge with special attention to low literacy and inclusion of pictures.

### **Conclusion**

This EBP project addressed the PICOT question and two secondary outcomes including appropriate referral, provider assessment, and patient follow-up compliance to the podiatry clinic. This EBP project answered the question posed by the PICOT: In adult diabetic patients ages 18-74 seen in the primary care setting, does a multi-faceted intervention, compared to previous clinic foot practices result in referrals that are more appropriate, improved provider assessment, and increased patient compliance with follow-up appointments over a 12-week period? The evidence-based multi-faceted intervention included: (a) implementing provider history and foot physical assessment including provider use of the Semmes-Weinstein Monofilament (SWM) tool to assess for actual diabetic foot complication, (b) assessing footwear, (c) providing patient education, and (d) multidisciplinary care by educating clinicians, planning a workflow, and providing ongoing feedback.

As a result of this project, there was a statically significant improvement in the number of appropriate referrals with use of the SWM tool versus the number inappropriate referrals that were placed prior to the intervention implementation. There was also a statically significant improvement in the number of provider assessments being completed post implementation as

compared to previous. Additionally, patients who were assessed were more compliant with follow up to the podiatry clinic compared to patients who were never assessed prior to the intervention.

It is imperative that provider foot risk assessment is consistently performed by every PCP in the primary care clinic to reduce the number of patients at risk for foot complication. This project showed that use of the evidence-based recommendations can lead to improved foot health in patients with diabetes. This project has demonstrated that the incorporation of provider foot assessment in primary care is an investment in the patient, the clinician, the organization and the future. The doctorally prepared nurse possesses the necessary leadership qualities to lead change by working collaboratively with the bedside nurse and delivering enhanced education and the professional support necessary to improve clinical practice (Morgan & Somera, 2014).

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**BIOGRAPHICAL MATERIAL****Shelby D. Strong**

Shelby D. Strong graduated from the College of Lake County with an Associate Degree in Nursing in December 2001. As a new graduate, she worked as a Registered Nurse in the Emergency Department of a busy Level One Trauma Center in Evanston, Illinois. In 2002, Shelby returned to school at Saint Xavier University (SXU) to continue her education and in May 2004 she graduated with honors with a Bachelor of Science Degree in Nursing. Later that same year, Shelby transitioned her employment to the Cook County Health and Hospital System (CCHHS) and continued providing direct care to patients in both the Adult Emergency Department and Trauma Specialty Care Unit. In 2008, Shelby returned to SXU and completed her Master of Science Degree in Nursing and in May 2011, she graduated as a Family Nurse Practitioner. In 2015, Shelby was one of four clinicians only two of whom were Advanced Practice Nurses selected as champion committee members to represent the CCHHS in Boston, Mass., at The American College of Physicians (ACP) Internal Medicine conference where she received recognition for her contributions of clinical work focused on Diabetes care. In 2016, Shelby was a contributing author to an article entitled, "Medication Adherence: Truth and Consequences" a featured symposium article focused on the provision of Diabetes Education for primary healthcare professionals which was published in *The American Journal of The Medical Sciences*. A passion for learning and with a burning desire to contribute to the future of nursing, in Dec 2018, Shelby successfully completed the Certified Nurse Educator Program (CNE) at Valparaiso University. In March 2019, she participated in the study abroad program and traveled to Chiang Mai, Thailand which afforded her the opportunity to learn more about cultural diversity and healthcare abroad. Shelby is currently attending Valparaiso University to earn her Doctor of Nursing Practice degree with an anticipated graduation date in May 2020. Shelby is a member of Sigma Theta Tau International Honor Society of Nursing, Alpha Omicron Chapter, The American Academy of Nurse Practitioners (AANP) and an affiliate member ACP. Currently, she is employed full time as a Family Nurse Practitioner in the adult General Medicine Clinic of the Cook County Health and Hospital System in Chicago, Illinois. As the single mother of three children, upon completion of the program, Shelby plans to focus on family, health and travel.

**ACRONYM LIST**

ABI: Ankle Brachial Pressure Index

ACA: Affordable Care Act

ADA: American Diabetes Association

APN: Advanced Practice Nurse

CDC: Center for Disease Control

CEPC: Center for Excellence in Primary Care

CINAHL: Cumulative Index to Nursing and Allied Health Literature

CMAPP: Context Message Audience Purpose Product

CPG: Clinical Practice Guidelines

DFN: Diabetic Foot Neuropathy

DFU: Diabetic Foot Ulcer

DNP: Doctor of Nursing Practice

DP: Dorsal Pedal

DPN: Diabetic Peripheral Neuropathy

DM: Diabetes Mellitus

EBP: Evidence Based Project

EMR: Electronic Medical Record

FNP: Family Nurse Practitioner

GMC: General Medicine Clinic

HCP: Health Care Provider

HEDIS: Healthcare Effectiveness Data and Information Set

HgbA1C; Hemoglobin A1C

HIPPA: Human Insurance Portability Act

ID: Identification

IRB: Institutional Review Board

IT: Information Technology

JBI: Joanna Briggs Institute

JHNEBP: John Hopkins Nursing Evidence-Based Practice

LEA: Lower Extremity Amputation

LMS Learning Module Software

LOPS: Loss of Protective Sensation

MEDLINE: Medical Literature Analysis and Retrieval System Online

NCQA: National Committee for Quality Assurance

NP: Nurse Practitioner

PAD: Peripheral Artery Disease

PC Podiatry Clinic

PCP: Primary Care Provider

PRISMA: Preferred Reporting Items for Systematic Reviews

PT: Posterior Tibia

PSSD: Pressure Specified Sensory Device

PL: Project Leader

QI: Quality Improvement

QOL: Quality of Life

RCW: Removable Cast Walker

RCT: Randomized Control Trial

SWM: Semmes-Weinstein Monofilament

TCC: Total Contact Cast

TRIP: Turning Research into Practice

US: United States

VPT: Vibration Perception Threshold

WHO: World Health Organization

Appendix A

Summary of the Evidence

<b>Citation</b>	<b>Purpose</b>	<b>Design/Level Quality Rating</b>	<b>Sample</b>	<b>Measurements/ Outcomes</b>	<b>Results/Findings</b>
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<p>ADA (2018)</p>	<p>To provide standards containing evidence-based recommendations most pertinent to the management of diabetes in primary care.</p>	<p>Clinical Practice Guideline  Level: I Quality: B</p>	<p>142 articles / resources (<a href="http://www.professional.diabetes.org">www.professional.diabetes.org</a>) from 2011 to include Standards in care app, 2019 update to ADA-EASD Management of Hyperglycemia, 2019 ADA-EASD Digital app consensus report, slide deck, Living Standards updates were utilized to compose this abridged supplement. Inclusion criteria: articles that focused on comorbid, coexisting diseases, age, education, disability and above all patients' values and preferences to guide treatment targets and strategies.</p>	<p>Standards of Medical care in diabetes were analyzed by the Professional Practice Committee (PPC) and Board of directors using ADA grading system ranging from Level A-E.</p>	<p>Foot ulcer and amputation represent major causes of morbidity and mortality in people with diabetes. Early recognition and treatment of patients with diabetes and feet at risk for ulcers and amputations can delay or prevent adverse outcomes. Recommendations include: Completion of a comprehensive foot evaluation at least annually to identify risk factors for ulcers and amputations, patients with evidence of sensory loss or prior ulceration or amputation should have their feet examined at every visit, obtain a prior history of ulceration, amputation, Charcot foot, angioplasty or vascular surgery, cigarette smoking, retinopathy and renal disease and assess current symptoms of neuropathy and vascular disease, foot exam should include examination of the skin, assessment of foot deformity, neurological assessment and vascular assessment of the foot and leg, patients with symptoms of claudication or decreased or absent pedal pulses should undergo ongoing preventative care and lifelong surveillance, provide general preventative foot care education to all persons with DM and use specialized therapeutic footwear for high risk individuals with DM.</p>
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<p>ADA (2019)</p>	<p>To provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care.</p>	<p>Clinical Practice Guideline  Level: I Quality: B</p>	<p>158 articles and resources (<a href="http://www.diabetesjournals.org/content/license">www.diabetesjournals.org/content/license</a>) from 1976-2017 were utilized to compose this diabetes care supplement. Inclusion criteria: articles that focused on comorbid, coexisting diseases, age, education, disability and above all patient s' values and preferences to guide treatment targets and strategies.</p>	<p>Standards of Medical care in diabetes were analyzed by the Professional Practice Committee (PPC) and Board of directors using ADA grading system ranging from Level A-E.</p>	<p>Recommendations include: Completion of a comprehensive foot evaluation at least annually to identify risk factors for ulcers and amputations, patients with evidence of sensory loss or prior ulceration or amputation should have their feet examined at every visit, obtain a prior history of ulceration, amputation, Charcot foot, angioplasty or vascular surgery, cigarette smoking, retinopathy and renal disease and assess current symptoms of neuropathy and vascular disease, foot exam should include examination of the skin, assessment of foot deformity, neurological assessment and vascular assessment of the foot and leg, patients with symptoms of claudication or decreased or absent pedal pulses should be referred for ankle brachial index and further vascular testing, multi-disciplinary approach is recommended for individuals with foot ulcer and high risk feet, refer patients who smoke who have prior history of lower extremity of complications, loss of protective sensation, structural abnormalities or peripheral arterial disease to foot care specialists for ongoing preventative care and life long surveillance, provide general preventative foot care education to all persons with DM and use specialized therapeutic footwear for high risk individuals with DM.</p>
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<p>Adiew ere et al. (2018)</p>	<p>To determine the effectiveness of patient education in preventing and reducing the incidence or reoccurrence of foot ulcers in adults with diabetes.</p>	<p>Systematic Review and meta-analysis.  Level: I Quality: A</p>	<p>Six RCTs from March 11, 2017-Sept 5, 2017. Inclusion criteria: participants ages 18 and over who have DM (type 1 or type 2) or those with DFU. Studies published in English and studies that the intervention was focused on patient education and the incidence of DFU post-educational intervention in addition to amputation rates post-educational intervention.</p>	<p>Health education using a brief versus an intensive educational approach was taught to patients diagnosed with diabetes to help them understand and become engaged in self-care management of their own health condition.</p>	<p>Overall, an intensive education approach offered a positive result in the reduction of DFU in the short term. RR=0.37, 95% CI 0.14, 1.01 (P=0.05) with a high heterogeneity of 91%</p>
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<p>Boulton et al. (2008)</p>	<p>Technical review of preventive foot care address and concisely summarize diagnostic testing to assist in identifying patients at risk for foot ulceration and to recommend what should be included in the comprehensive foot exam for adult patients with diabetes.</p>	<p>Task Force Report  Level: IV Quality: B</p>	<p>ADA Foot Care Interest Group (immediate, past and current co-chairs of the ADA Foot Care Interest group, primary care, orthopedic and vascular surgery, physical therapy, podiatry medicine and surgery and the American Association of Clinical Endocrinologists) reviewed articles (total number not provided) that included data on preventative care, diagnostic testing to identify patients at risk for foot ulceration and the various types of screening (dermatological, musculoskeletal, and neurological) that should be performed in clinical practice.</p>	<p>The lifetime risk of a person with diabetes developing a foot ulcer verses the annual incidence of foot ulcers.</p>	<p>All patients with diabetes must have their feet evaluated at least at yearly intervals for the presence of predisposing factors for ulceration and amputation (neuropathy, vascular disease, and deformities).</p>
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<p>Feitos a et al. (2016)</p>	<p>To verify the degree of reliability of the Semmes-Weinstein monofilament as a risk assessment tool for diabetic foot.</p>	<p>Integrative Review  Level: III Quality: B</p>	<p>Five Cross Sectional and one Cohort study from 2010-2015. Inclusion criteria: studies published in English, Portuguese and Spanish.</p>	<p>To compare the degree of reliability of the Semmes-Weinstein monofilament as a risk assessment tool versus reliable alternatives and to compare the functionality of other devices to the Semmes-Weinstein monofilament. The other devices included the Pressure-Specified Sensory Device (PSSD), Electrical perception threshold testing (EPT) and the angiocatheter.</p>	<p>The Semmes-Weinstein monofilament is a reliable tool which has the best performance for assessing the risk for diabetic foot.</p>
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<p>Feng et al. (2011)</p>	<p>To evaluate current evidence regarding the prognostic value of the Semmes-Weinstein monofilament examination (SWME) in predicting foot ulceration and LEA in patients with DM.</p>	<p>Systematic Review  Level: II Quality: B</p>	<p>Nine Prospective Cohort studies were obtained on Nov 15, 2009. Inclusion criteria: the study quantified the predictive value of the SWME and data on ulceration and lower extremity amputation (LEA) during follow-up were described for patients with negative and positive SWM results.</p>	<p>Assessing and associating the SWME result with risk for ulceration or LEA during follow up.</p>	<p>A positive SWME result is a significant predictor of future ulceration and likely LEA in patients with DM. If diabetic patients have a positive SWME, their chances of ulceration increase with 10 to 20%, corresponding to 2.5 to 5 times higher risk than patients with normal sensation as determined by SWME. Risk of LEA increases with 5 to 15% corresponding to 1-5 to 15 times higher risk for patients with DM with positive SWME. than those with negative SWME results</p>
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<p>Formosa et al. (2016)</p>	<p>To evaluate the current guidelines for foot screening in patients with diabetes and to examine their relevance in terms of advancement in clinical practice, improvement in technology, and change in socio-cultural structure.</p>	<p>Clinical Guideline  Level: I Quality: B</p>	<p>Ten complete diabetes foot screening guidelines from Jan 2011-Jan 2015. Inclusion criteria: guideline and research evidence published in English that addressed aspects of diabetic foot screening, management prevention and education relating to foot care of people with type 2 diabetes.</p>	<p>Several grading and ranking systems were utilized to rate the underlying evidence of guidelines to include Own (NHMRC), Own (CDA), Own (NICE), Agency for healthcare Policy and Research (AHCP), Own (SIGN), Grading Recommendations Assessment, Development and Evaluation (GRADE) system, Own (ADA), own, (IDF). Reviews were related to topics to include: prevention, footwear, PAD diagnosis, PAD prognosis, PAD therapy, infection and wound healing.</p>	<p>Guidelines are inconsistent in how they rate quality of evidence and grade strength of recommendations. As a result, guideline users may find it difficult to understand the messages that rating systems are trying to communicate. All 10 guidelines included data related to peripheral neuropathy, peripheral vascular disease, inspection and provision of footwear, foot deformity, patient foot education and frequency of assessment and screening. Areas where guideline content varied included: evaluation of limited joint mobility, training for health professionals, self-monitoring and inspection of feet by health personnel, multi-disciplinary team within a diabetic foot care service for inspection of diabetic feet.</p>
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<p>Martin s de Oliveira &amp; Moore (2015)</p>	<p>To compare the literature on strengths and limitations of different offloading devices in the treatment of diabetic foot ulcers.</p>	<p>Systematic Review  Level: III Quality: A</p>	<p>Fifteen Studies (Nine RCTs and Three Systematic Reviews) from 1976-2008. Inclusion criteria: studies in English or Portuguese, where different types of casts, therapeutic shoes and other orthotic devices have been compared and analyzed in adult patients with diabetic foot ulcers (DFU) were included.</p>	<p>Primary outcome measure was ulcer healing rate in terms of the percentage of ulcers healed, healing time and reduction in ulcer size. Secondary outcome measures were: adverse effects, or any other effect that could be attributed to the use of the offloading device; adherence; cost and QOL.</p>	<p>The total contact cast (TCC) is the best offloading device for the treatment of DFUs, followed by instant total contact cast (iTCC) and Removable Cast Walker (RCWs).</p>
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<p>Sharoni et al. (2016)</p>	<p>To assess the effectiveness of health education programmes to improve foot self-care practices and foot problems among older people with diabetes.</p>	<p>Systematic Review  Level: II Quality: B</p>	<p>Fourteen studies (Four RCTs, six non-randomized control trials, one NRS, for which the type of the design could not be determined) from Jan 2000-March 2015.</p>	<p>Health education programs were programs designed to teach older adults the importance of practicing foot self-care and controlling foot problems. Outcomes measured included foot self-care (e.g. inspection, hygiene, appropriate socks and shoe, nail care, professional treatment), self-efficacy, empowerment, problem solving, knowledge, acculturation, medication adherence, social support, emotional support, anxiety and depression, quality of life, diabetes healthcare utilization, and satisfaction with care. The secondary outcomes included clinical findings or signs and symptoms of foot problems (e.g. assessed for peripheral neurologic assessment, vibration perception threshold, pain and disability, morbidity, ulcer, lesion, amputation, tinea pedis and callous). Other significant outcomes specific to diabetes were also measured, such as self-monitoring of blood glucose, fasting blood sugar, glycosylated</p>	<p>All education programs implemented by the previous researchers showed improvement in foot self-care scores and foot problems (such as neuropathy, foot disability, foot score, treatment session, lesion, tinea pedis and callous grade) among older adults with diabetes. However, owing to different methodological approaches, populations, settings, outcomes measured, follow up and evaluation, the findings need to be taken into consideration. The strategies in health education, such as foot assessment, verbal and written instruction, discussion, counseling, problem solving, social support, home visits and phone calls proved to significantly improve the effect of education programs.</p>
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				hemoglobin a1c, lipid profile, blood pressure, body mass index, waist circumference, retinal examination and urinalysis.	
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<p>van Acker et al. (2014)</p>	<p>To assess the economic and quality of life burden of diabetic foot disorders and to identify disparities in the recommendations from guidelines and the current clinical practice across EU5 (Spain, Italy, France, UK and Germany).</p>	<p>Systematic Literature Review  Level: III Quality: A</p>	<p>Eleven Systematic Reviews (Six studies on economic burden, and resource utilization, five studies on QOL) from 2000-Oct 2011. Studies reporting cost, resource utilization and QOL associated with diabetic foot complication, studies reporting data for adult patients at high risk for diabetic foot problems in any care setting, studies in English and studies reporting current clinical pattern for diabetic were eligible if they reported objectivized data on component variable of multidisciplinary diabetic foot care such as referral rate, vascular imaging frequency.</p>	<p>Measure economic and QOL burden of diabetic foot disorders according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines.</p>	<p>Guidelines indicate effective management of DM leading to prevention of amputations as the major cost and QOL driver. Results indicate that there is underuse of imaging, revascularization and referrals to specialists. There is an unmet need to reinforce the guideline to obtain favorable outcomes in terms of preventing diabetic foot complications to the extent possible and achieving limb salvage where diabetic where diabetic foot complications are unpreventable.</p>
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<p>Wang et al. (2017)</p>	<p>To evaluate the diagnostic accuracy of monofilament tests for detecting diabetic peripheral neuropathy.</p>	<p>Systematic Review and Meta-analysis  Level: III Quality: B</p>	<p>Nineteen comparative trials from 1997-2015. Inclusion criteria: a) the study examined the diagnostic accuracy of a monofilament test for detecting DPN, b) the article was published in English, c) the study provided sufficient data.</p>	<p>Measuring sensitivity of the monofilament tool compared to other trials using nerve conduction studies (NCS) as the reference standard; vibration perception therapy (VPT), neuropathy disability score or the Michigan Neuropathy Screening Instrument (MNSI).</p>	<p>The pooled sensitivity and specificity of monofilament tests for detecting DPN were 0.53 (95% CI 0.32 to 0.74) and 0.88 (95% CI 0.78 to 0.94%). The 5.07/10g Semmes-Weinstein monofilament seemed to be a screen with limited sensitivity for DPN in primary care settings based on current available evidence.</p>
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## Appendix B

**DIABETIC FOOT EXAM TIP SHEET****Remember *TIPS***

**T**- Temperature, turgor

**I** – Inspect, integrity

**P** – pulses, palpate

**S** – Sensation strength

Sites for sensation assessment include:

1,3,5 - toes

1,3,5 - metatarsal

Outside and inside of arch

Heel

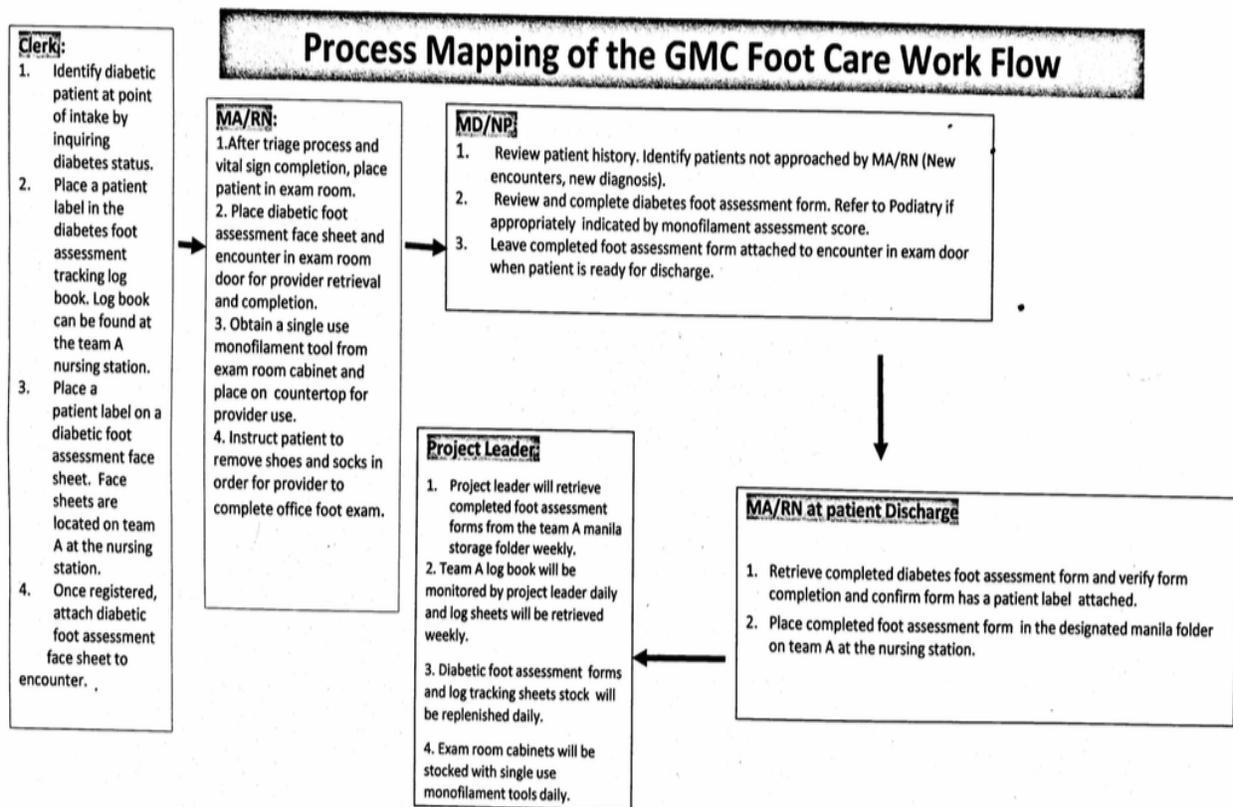
On top, first inner space – testing the deep peroneal nerve strength

Note the location and size of any injuries, lesions etc.

Please see instructional provider video tutorial at [http://cchhs1-my.sharepoint.com/:v:/g/personal/dvittum\\_cookcountyhhs.org/EdPi\\_i2WitPu9bEd\\_uQm4BuVPabB2ctg605s7LCr0lva?e=9idpUG](http://cchhs1-my.sharepoint.com/:v:/g/personal/dvittum_cookcountyhhs.org/EdPi_i2WitPu9bEd_uQm4BuVPabB2ctg605s7LCr0lva?e=9idpUG))

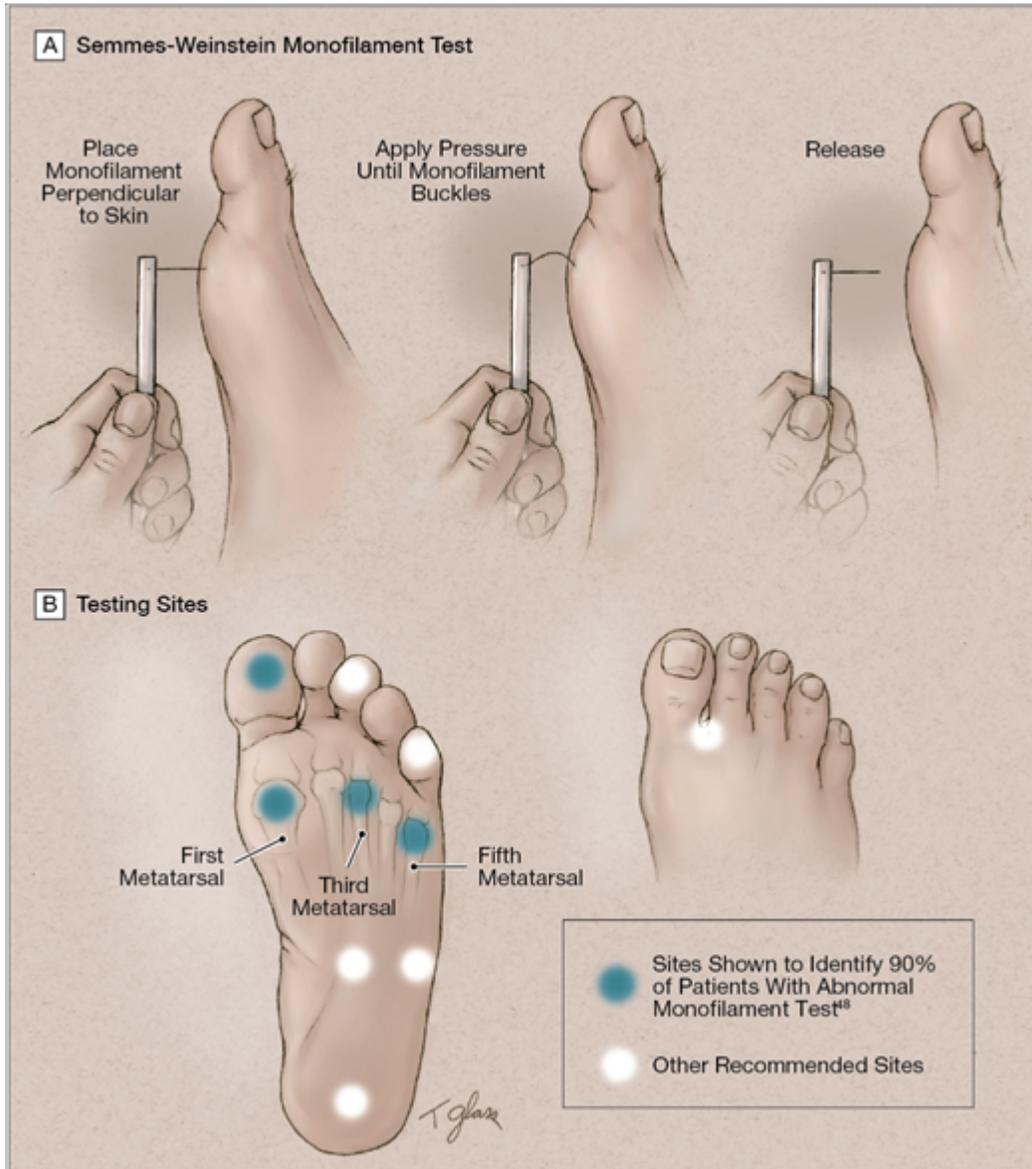
Appendix C

Workflow Algorithm



Appendix D

SEMMES WEINSTEIN MONOFILAMENT TEST



Singh, N., Armstrong, DG., Lipsky, BA. (2005). Preventing foot ulcers in patients with diabetes. *JAMA*. 293(20):217-228

## Appendix E

## THE COMMON PERONEAL NERVE

## The Common Peroneal Nerve

- Superficial peroneal nerve
  - Motor functions
    - Foot eversion
- Deep peroneal nerve
  - Motor functions
    - Foot dorsiflexion, toe extension

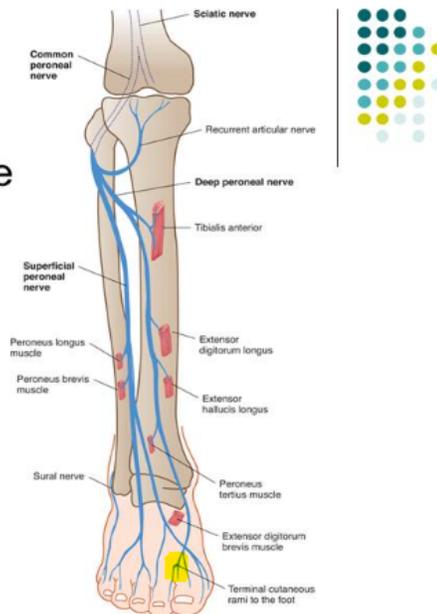


Figure 28-16 . The common peroneal nerve (L4, 5; S1, S2). In: Waxman SG. *Clinical Neuroanatomy*. 26<sup>th</sup> ed. New York, NY: McGraw-Hill; 2010. <http://www.accessphysiotherapy.com>. Accessed March 22, 2012.

Singh, N., Armstrong, DG,, Lipsky, BA. (2005). Preventing foot ulcers in patients with diabetes. *JAMA*. 293(20):217-228

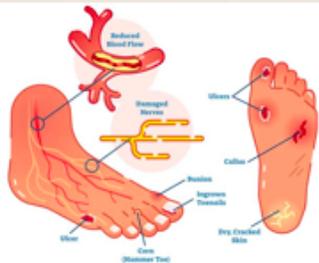
Appendix F

PATIENT SELF-CARE FOOT EDUCATION PAMPHLET

**Diabetic Foot Complication**

Individuals diagnosed with diabetes are at risk for developing diabetic foot complication. Signs and symptoms of this condition may include:

- Peripheral Neuropathy
- Peripheral Vascular Disease
- Skin Changes & Poor Circulation
- Development of Corns & Calluses
- Foot pain, Sores, Lesions or Blisters
- Foot Ulcers and Amputation



<http://flickr.com>



PLEASE SEE A STAFF PERSON WITH ANY QUESTIONS CONCERNING DIABETIC FOOT CARE OR FOR ADDITIONAL INFORMATION REGARDING OUR

DIABETIC PATIENT CARE SERVICES

**If signs of diabetic foot complication occur:**

Inform the staff at your next visit of any new foot concerns you may be experiencing.

Be seen in the nearest emergency department for any symptoms of persistent fever, chills, pus, drainage or foul odor from foot sores.

Special Acknowledgements:  
 Shirley D. [redacted] RN, MSN, FNP-BC, Director, Team Leader  
 Nancy Johnson, PhD, RN, CDE, Program Advisor  
 Patricia L. Smith MD, Director, Staff Educator



<https://flickr.com>

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 Gors, October 28) Diabetic Foot Image Credits. nhari.stor.adobe.com

**DIABETIC FOOT CARE**



<http://flickr.com>

Recommendations to reduce the risk for the development of diabetic foot complication.



A comprehensive foot exam at least annually is recommended for persons diagnosed with diabetes



<https://flickr.com/>

**Foot Self Care Recommendations:**

- **Inspect your feet daily**
- Bathe feet in lukewarm, but never hot water**
- Moisturize your feet but not between your toes**
- Obtain a foot exam at least annually that includes provider provision of patient foot risk assessment**
- Cut nails carefully**
- Never treat corns or calluses yourself**
- Wear clean, dry socks**
- Never walk barefoot**
- Do not smoke**
- Inform your provider of any new changes in your feet**

**DIABETIC FOOT SELF-CARE GUIDE**

Thorough diabetic foot care and consistent healthy foot care practices can help reduce the risk for the development of diabetic foot complication.

**MULTIDISCIPLINARY TEAM APPROACH TO DIABETES FOOT CARE:**  
 Use of a multidisciplinary team approach to the provision of diabetic foot care promotes: sooner identification, regular inspection and examination of the at risk foot. Additionally, this care approach reinforces metabolic control and regimen compliance.



Team based care



Patient centered care approach

**FOOT AND SKIN CARE:**  
 Individuals with diabetes are prone to skin problems. It is important to inspect the feet daily to monitor for the presence of cuts, abrasions, dry skin, sores, edema, skin color and skin temperature changes.



Healthy foot care practices



Inform your provider of any new foot changes

**PROTECTIVE FOOTWEAR:**  
 Wearing specially designed shoes can help reduce the risk for diabetic foot complication and can help to promote healthy circulation in the feet of individuals diagnosed with



Ask about custom footwear



Avoid the use of ill fitting shoes

<https://flickr>

## Appendix G

## Intake Variable Form

## Intake Variable Form

Identifier: \_\_\_\_\_

Pre Group: \_\_\_\_\_ Intervention Group: \_\_\_\_\_ Post-Intervention Group: \_\_\_\_\_

Age: \_\_\_\_\_ Gender: \_\_\_\_\_

Race: AA \_\_\_\_\_ Caucasian: \_\_\_\_\_ Hispanic: \_\_\_\_\_ Polish: \_\_\_\_\_ Asian: \_\_\_\_\_ Other: \_\_\_\_\_

Marital Status: Single: \_\_\_\_\_ Married: \_\_\_\_\_ Divorced: \_\_\_\_\_ Widowed: \_\_\_\_\_

Years Diabetic: \_\_\_\_\_

Serum Hgba1c: \_\_\_\_\_

Foot Exam by Provider: Yes: \_\_\_\_\_ No: \_\_\_\_\_

Monofilament Tool Score: \_\_\_\_\_

Referral to Podiatry: Yes: \_\_\_\_\_ No: \_\_\_\_\_

Patient Podiatry Appointment Compliance: Yes: \_\_\_\_\_ No: \_\_\_\_\_

History of Single Limb Amputation: Yes: \_\_\_\_\_ No: \_\_\_\_\_

Clinic Provider Type: MD: \_\_\_\_\_ NP: \_\_\_\_\_

Insurance Type: Self Pay \_\_\_\_\_ Medicaid: \_\_\_\_\_ Medicare: \_\_\_\_\_ Private: \_\_\_\_\_

Appendix H

**ACTUAL PROJECT TIMELINE**  
**Fall 2019/Spring 2020**

Fall 2019 Semester Weeks	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Project proposal	x															
IRB Approval		x														
Pre-Intervention Data Collection			x	x	x	X		x	x	X	x	x				
Clinician Education											x	x	X	x	x	x
Intervention Phase											x	x	X	x	x	x

Spring 2020 Semester Weeks	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Intervention Phase	x	x	x	x	x	X										
Post Intervention Phase										X	x	x				
SPSS Data Entry								x	x	X	x	x				
Data Analysis													x	X		
Dissemination Phase																
Abstract						X	x									
Biography			x	x	x											
Poster Preparation											x	x	x			
Presentation				x										X		

Appendix I

CITI PROGRAM SOCIAL BEHAVIORAL EDUCATIONAL RESEARCHERS CERTIFICATE



Completion Date 21-Apr-2019  
Expiration Date N/A  
Record ID 31372860

This is to certify that:

**Shelby Strong**

Has completed the following Citi Program course:

**Group 1: Social Behavioral Educational Researchers** (Curriculum Group)  
**Group 1: Social Behavioral Educational Researchers** (Course Learner Group)  
**1 - Basic Course** (Stage)

Under requirements set by:

**Valparaiso University**



Verify at [www.citiprogram.org/verify/?wd4b94d10-3c83-471c-a750-eded0ce329d6-31372860](http://www.citiprogram.org/verify/?wd4b94d10-3c83-471c-a750-eded0ce329d6-31372860)

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Appendix J

HUMAN PARTICIPANTS IN RESEARCH CERTIFICATE



COOK COUNTY HEALTH & HOSPITALS SYSTEM  
Office of Research & Regulatory Affairs  
1950 W Polk, Room 9303, Chicago, IL 60612  
Betty Donoval, JD, MS, Interim Director

Toni Preckwinkle  
President, Cook County Board of Commissioners  
John Jay Shannon, MD  
Chief Executive Officer, Cook County Health

*Shelby Strong APN*

has successfully completed the  
Cook County Health  
training on the use of

*Human Participants in Research*

Handwritten signature of Stacey Kincaid in cursive.

Stacey Kincaid, MPH  
Informed Consent Coordinator  
Research & Regulatory Affairs

07/18/2019  
Date